Attachment 1: Additional Questions for the Record
Robert Califf, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration

The Honorable Cathy McMorris Rodgers

1. **Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER) has stated on numerous occasions[14] [15] his plans to create an Operation Warp Speed-lookalike program, specific for rare diseases. Please elaborate on these plans.**

CBER is steadfastly committed to working with stakeholders, including other government agencies, academia, industry, and product manufacturers, to foster beneficial innovation in the field of cell and gene therapies to help make the development, review, and approval of these innovative products more efficient, and to bring their benefits to patients sooner.

As we continue to develop an evidence-based framework for these products, the Food and Drug Administration (FDA or the Agency) understands that we may need to re-evaluate and modernize our approach to the unique challenges of these products, while also helping to ensure the resulting therapies are both safe and effective. FDA views rare disease gene therapy as an excellent starting point for the communications with sponsors needed to expedite the delivery of potentially life-saving therapies to patients.

In this regard, there are indeed steps that could be taken toward more efficient gene therapy product development. Sharing best manufacturing practices among academic and industrial developers could result in advances associated with better product quality, including consistency and yield, along with reduced costs. Additionally, there is significant divergence among global regulators in the quality and safety standards for the evaluation and regulation of cell and gene therapy products.

The proposed communication pilot that CBER intends to launch later this year will focus on the development of therapies for rare diseases. We hope to build off the experience CBER gained with accelerated vaccine development as part of Operation Warp Speed during the pandemic. The purpose of the pilot communication project will be to attempt to further accelerate the pace of development of cell and gene therapy products for very small populations with high medical need who have no satisfactory alternatives. CBER anticipates that eligible products will include therapies meeting the threshold criteria as explained in the expedited program guidance for regenerative medicine advanced therapy or breakthrough therapy designations preparing to enter pivotal clinical trials. FDA plans to solicit applications for participation in the pilot through a Federal Register Notice. CBER anticipates that, if selected for the pilot, sponsors will be given an initial meeting to review features of the program and discuss pathway toward approval; following that meeting, additional ongoing informal interactions via email or teleconference would take place on an as-needed basis as agreed upon by the sponsor and FDA. Evaluation of the pilot program would take place at regular intervals to make appropriate adjustments and to assess whether the intended objectives were being achieved. This pilot is intended to complement other actions that CBER is undertaking to accelerate product development, including further facilitating the use of

accelerated approval, when appropriate, and working toward global regulatory collaboration to facilitate product access.

2. **Please explain the benefits of such a program and the reasons for emulating Operation Warp Speed, including the specific elements and successes of Operation Warp Speed that would prove beneficial to the rare disease pipeline.**
    A. **What specific rare diseases would the program focus on?**
    B. **How would FDA choose which rare diseases to focus on?**
    C. **Would such a program require an authorization from Congress?**
    D. **What funding would be utilized to operationalize and execute such a program?**

The pilot program that CBER plans to undertake will address challenges that have led to delays in the advancement of cell and gene therapy product development and will focus on the full spectrum of serious or life-threatening rare diseases affecting very small numbers of individuals each year in this country (ranging from one to a few hundred) that currently have no acceptable treatment alternatives. FDA plans to publish a *Federal Register* Notice announcing the pilot and requesting applications for participation in it. We anticipate choosing a small number of programs that show promise in early clinical development for participation. Care will be taken to ensure that a fair representation across the spectrum of rare diseases is maintained. For this pilot program no authorization is necessary from Congress, and funding would be drawn from CBER's current operating budget authority.

The Honorable Brett Guthrie

1. **Commissioner Califf, we are concerned after a recent Wall Street Journal article highlighted recent holds placed on potentially curative treatments for Sickle Cell Disease and Type 1 Diabetes as well as the increase in clinical holds compared to the number of applications for approval submitted. What steps is leadership at the Agency taking to address the ongoing and growing performance issues at CBER, and more specifically, OTAT? Specifically, how will the recently redesigned "Super" Office of Tissue Products improve the quality and efficiency of sponsor interactions?**

Over the past several years, CBER has experienced an exponential growth in cellular and gene therapy applications with limited staffing increases. This presented severe challenges and resulted in performance issues for some areas.

The Office of Tissues and Advanced Therapies (OTAT) has experienced unprecedented growth because of rapid advances in the cell and gene therapy industry, and the need for additional CBER leadership and technical staff are drastically increasing. In 2021, CBER and OTAT leadership undertook an analysis and review of OTAT's organizational structure and determined that it needed to address the current and anticipated increases in funding and staff to meet the rapidly evolving cell and gene therapy industries. This structural assessment was further analyzed by a third-party consulting firm to ensure best practices and organizational suitability. From this assessment came several critical recommendations, including the move to a new super office structure.

As a part of CBER's reorganization efforts, OTAT will transition into a super office, the Office of Therapeutic Products (OTP) in February 2023. With a more robust structure, OTP will be better positioned to handle the current and future programmatic demands, increase efficiency, improve quality of services, streamline processes, and make better use of resources. The structure of the super office will allow for greater capacity for current and future growth while aligning teams and functions in a way that promotes efficiencies in the long term.

PDUFA VII provides for a substantial increase in staff in the cellular and gene therapy program, and CBER is actively recruiting staff in a competitive marketplace. To carry out our vital public health mission, it is necessary for the Center to routinely evaluate its organizational structure to be ready to address the rapidly evolving scientific and medical product landscape.

The Agency is committed to supporting the development of this rapidly emerging field. This reorganization within CBER is intended to help the Agency follow the growth in cell and gene therapy, to increase the focus on manufacturing, and to facilitate timely responses to sponsors developing novel products for serious conditions with unmet medical needs.

The Honorable Gus Bilirakis

1. **The White House announced that it would be ending the COVID-19 public health emergency declaration on May 11, 2023. The FDA states that despite this, "the ending of the public health emergency declared by HHS under the Public Health Service Act will not impact FDA's ability to authorize devices (including tests), treatments or vaccines for emergency use. Existing emergency use authorizations (EUAs) for products will remain in effect and the agency may continue to issue new EUAs going forward when criteria for issuance are met." Can the FDA explain the distinction between these two authorities, which one(s) will be ended on May 11, and what FDA plans to do in response to the sunset of the COVID-19 pandemic?**

Under section 319 of the Public Health Service (PHS) Act, the HHS Secretary can issue a determination (also referred to as a "declaration") that a "public health emergency" (PHE) exists.

The COVID-19 PHE declared under section 319 of the PHS Act has allowed FDA to provide important tools and flexibilities to manufacturers, health care facilities, providers, patients, and other stakeholders.

- The declaration generally lasts for 90 days, but may be extended by the Secretary. After each extension, the declaration lasts for 90 days or until the Secretary declares the emergency no longer exists, whichever occurs first.
- A section 319 PHE declaration allows HHS to take appropriate actions in response to the emergency consistent with other authorities, including making grants; entering into contracts; and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder. For a more comprehensive list of what this type of declaration can enable, see HHS: Public Health Emergency Declaration.[1]

[1] https://aspr.hhs.gov/legal/PHE/Pages/Public-Health-Emergency-Declaration.aspx

- A section 319 PHE declaration does not enable FDA to issue EUAs.
- HHS issued a section 319 PHE declaration in January 2020, and has extended it every three months since.

Separate declarations – sometimes referred to as "EUA declarations" – under section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act (also issued by the HHS Secretary) enable the issuance of EUAs.

Specifically, before FDA can issue an EUA, the HHS Secretary must declare that circumstances exist justifying an authorization. An EUA declaration is based on specific types of determinations, also under section 564, of emergencies/threats or significant potential emergencies/threats by the Secretaries of HHS, Homeland Security, or Defense.

- Unlike the section 319 PHE declaration that expires if not extended, an EUA declaration under section 564 generally continues until the HHS Secretary terminates it.
- An EUA declaration is distinct from, and not dependent on, a HHS PHE declaration under section 319 of the PHS Act, and, therefore, an EUA may remain in effect beyond the duration of the section 319 PHE declaration if all statutory conditions are met.
- Products may remain authorized and new EUAs may continue being issued so long as the applicable EUA declaration remains in effect and the EUA is not revoked.
- HHS issued a determination under section 564 (initially issued on February 4, 2020) that there is public health emergency, or significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus (nCoV) in 2019 (COVID-19). Based on its determination, HHS issued four EUA declarations, for certain
    - *In vitro* diagnostics;
    - Personal respiratory protective devices;
    - Medical devices and alternative products used as devices; and
    - Drugs and biological products.
- These declarations that refer to the February 4, 2020, determination have not been terminated by the Secretary because, among other things, the circumstances described in section 564(b)(1) continue to exist – i.e., COVID-19, a disease attributable to SARS-CoV-2, continues to present a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad.

If the Secretary terminates an EUA declaration, then any EUAs issued based on that declaration will cease to be in effect, and FDA may no longer issue EUAs for products based on that declaration. If an EUA declaration is terminated, notice of termination will be published in the *Federal Register*. Before an EUA declaration is terminated, the Secretary will issue a Federal Register notice providing advance notice to the public that the EUA declaration is being

terminated. This starts the transition, which must be of a reasonable period to allow for proper dispositioning.

Importantly, the ending of the PHE declared by HHS under the PHS Act will not impact FDA's ability to authorize devices (including tests), treatments or vaccines for emergency use. Existing EUAs for products will remain in effect and the Agency may continue to issue new EUAs going forward when criteria for issuance are met.

FDA will publish a notice addressing the Agency's COVID-19-related guidance documents,[2] including which of those guidance documents will no longer be in effect after the expiration of the PHE declared by HHS under the PHS Act, and which of those guidance documents FDA is revising to temporarily continue in effect.

FDA remains committed to providing notice and information to all impacted stakeholders to ensure a smooth transition.

More information is available on our website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends.

2. I have heard concerns from constituents and stakeholders that the Center for Biologics Evaluation and Research (CBER) has too often delayed clinical trial protocols and development for therapies in the pipeline, causing innovators to look to regulatory agencies outside the US to review and approve products more efficiently than the FDA. Is FDA leadership concerned by the implications of many foreign regulators outperforming CBER?

As a general matter, FDA is prohibited by law from disclosing information regarding pending applications before the Agency (see 21 CFR 601.50 and 601.51). However, we hope the following general information is helpful in addressing the clinical hold issues mentioned in the constituent's inquiry.

A clinical hold is an order issued by FDA to a sponsor of an IND application to delay a proposed clinical investigation or to suspend an ongoing investigation. All or some of the investigations conducted under an IND application may be placed on clinical hold. More information related to grounds for clinical hold can be accessed on FDA's website at https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold.

Many of the products that CBER regulates are innovative and are the first of their kind. CBER works closely with sponsors to help facilitate the development of these innovative products. CBER also takes seriously its role in human subject protection and when warranted places clinical investigations on hold. In such cases, CBER works closely with the sponsors to resolve clinical holds when they must be issued.

[2] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

Please know that FDA works with all sponsors to resolve issues and help speed development of new products, while maintaining high, scientifically based safety and efficacy standards.

Regarding foreign regulators, CBER actively participates in discussions of advanced therapy medical products and collaborates with other regulatory agencies to share information and experiences in the International Pharmaceutical Regulators Program, Cell and Gene Therapies Working Groups. FDA also participates in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), which includes industry members, as well as other international organizations, in efforts to harmonize requirements and promote regulatory convergence. CBER also works with the EMA through the FDA-EMA Parallel Scientific Advice Program: General Principles EMA-FDA Parallel Scientific Advice (Human Medicinal Products).

3. **The agency recently announced a voluntary recall of one specific artificial tear product manufactured by Global Pharma Healthcare in Chennai, India. Per the announcement, the CDC first notified the agency about the instances of infection and death that it traced to the use of this product. When was the last time the agency inspected the manufacturing facility of Global Pharma Healthcare? As Global Pharma Healthcare reportedly manufactures numerous products in this facility, which has led to the contamination of at least of its consumer over-the-counter products, what is the response of the agency to ensure the safety of the other products? How will you commit to improving your foreign inspections efficiency and processes, particularly in China and India?**

Global Pharma Healthcare voluntarily recalled all lots within expiry of their Artificial Tears Lubricant Eye Drops, distributed by /EzriCare, LLC- and Delsam Pharma, to the consumer level, due to possible contamination. The Centers for Disease Control and Prevention (CDC) alerted FDA to an investigation of a multi-state cluster of Verona Integron-mediated Metallo-β-lactamase (VIM)- and Guiana-Extended Spectrum-β-Lactamase (GES)- producing carbapenem-resistant Pseudomonas aeruginosa (VIM-GES-CRPA) infections possibly associated with the use of the artificial tears manufactured by Global Pharma Healthcare. FDA initiated an unannounced inspection at Global Pharma Healthcare Private Limited in India in February 2023. This was the first FDA inspection at this location.

It is the firm's responsibility to take appropriate corrective actions to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist, and to ensure the safety and effectiveness of their products.
The Agency remains committed and continuously seeks to improve its foreign inspection efficiencies and processes. Over the past year, we sent U.S.-based FDA investigators on multiple details to FDA's foreign offices in order to limit travel from the United States to foreign sites and allow us to accomplish more inspections. We have also been obtaining one-year multi-entry visas for India for many of our pharmaceutical investigators. This has saved a significant amount of time and avoided delays encountered in having to apply for a visa for each inspection in India. We are looking to implement similar types of efficiencies for inspections in China.

Additionally, the foreign inspection planning process has shifted to become a more automated process. This automation allows FDA staff to better manage firm inspection activities and automates previously manual activities while tracking all trip coordination activities. This also allows for real-time mapping of inspection assignments, so that facilities that are located in close proximity to each other may be inspected on the same trip by the same inspection team, which could reduce travel and allow for a more efficient inspection trip.

4. **I'm sure you would agree that OTC medications play a critical role in providing consumers safe, effective, and affordable options for self-care. OTC drugs enable consumers to directly access needed medications without having to take off time from work or school for a doctor visit to secure a prescription. Additionally, utilization and availability of OTC products save millions of dollars for our healthcare system on an annual basis. The best way to ensure that OTCs are available to consumers in a timely way is for FDA and OTC makers to have in place efficient processes for resolving issues that arise during the drug development process so products can be approved without unnecessary delays.**

   The Office of Non-Prescription Drugs is converting most of its sponsor meetings from live to written responses to OTC product applicants. Their default is WRO – written response only – no opportunity to meet or speak by phone. These written responses are not adhering to PDUFA meeting goals, taking a minimum of 10 months, and usually longer, and with no opportunity for a dialog or to ask clarifying questions, except in writing back and again waiting for a response, which leads to more delay and lack of clarity.

   In order for America to be prepared for the next pandemic, we must have efficient processes, rooted in science, that permits FDA to make new, effective prescription and OTC treatments available to Americans. Could you please explain why this is happening, specifically at the Office of Non-Prescription Drugs, and your plans to address it and provide a more appropriate and efficient interaction with company applicants?

During the early years of the COVID-19 pandemic, the Office of Nonprescription Drugs (ONPD) played a key role in pandemic response, in areas such as facilitating greater availability of hand sanitizers, and evaluating large numbers of EUA requests. Also, in March 2020, Congress enacted the CARES Act, which included many statutory requirements for ONPD in the area of OTC Monograph reform. ONPD also had substantial staff shortages. ONPD had to shift resources to prioritize the PHE; one of the means ONPD used to still get non-COVID work done was the Written Response method of providing advice to drug sponsors, which is more efficient and generally faster than the procedures involved in live meetings. However, as the resource burden associated with the pandemic has lessened somewhat and ONPD has made progress in hiring, ONPD has now transitioned to offering the option of live meetings with sponsors seeking advice, and ONPD has improved the timeliness of scheduling meetings with sponsors according to management goals. ONPD expects continued progress over the coming year.

5. The COVID-19 pandemic showed us that delaying access to healthcare had devastating impacts on the health of Americans, and we must ensure that this does not happen. When people can take control of their everyday health through access to OTC medicines, whether it's to quit smoking or manage their allergies, they not only stay healthier, but also save on healthcare costs. Studies show that every dollar spent on OTC medicines saves the US health care system $7.33.

Unfortunately, applicants who are trying to switch a product from prescription to OTC have been waiting years for final approval in order to make them available to the American public. Some of these medicines are readily available OTC in 20 other countries, including the UK. Innovative switches are even more challenging and are taking even longer. Are you adequately staffed to handle this pipeline of applications for OTC products?

ONPD agrees that availability of new nonprescription drugs has the potential to improve self-care and public health. ONPD has long worked actively with sponsors who wish to switch drugs from prescription to nonprescription under the New Drug Application (NDA) system, or to develop new nonprescription drugs under the NDA system. Importantly, FDA recently released the proposed rule *Nonprescription Drug Product with an Additional Condition for Nonprescription Use*, often referred to as the ACNU rule. The ACNU rule, if finalized, would allow sponsors whose drug products pose challenges for a full Rx to OTC switch because labeling alone is not sufficient to ensure that the consumer can appropriately self-select or appropriately use, or both, a drug product correctly in a nonprescription setting, to use additional conditions of use, such as technology elements, to overcome the challenges posed by the complexities of these products. We expect that if the ACNU rule is finalized, sponsors of such products will complete development programs and submit NDAs using the process described in the finalized ACNU rule.

An important distinction between the United States and foreign countries with respect to nonprescription drugs is that, in foreign countries, many drugs that are characterized as nonprescription are not actually directly available to consumers, but rather are pharmacist-dispensed. This is in contrast to the U.S. system, in which OTC drugs are actually on retail shelves and readily available to consumers.

ONPD and its review divisions have faced staffing and hiring challenges, particularly as resource demands increased greatly with the COVID-19 pandemic and the need for implementation of the reforms of the OTC Monograph system, required under the CARES Act. While resource demands from the pandemic have lessened somewhat, demands related to OTC Monograph Reform and NDA drug development continue to increase, and ONPD and its review divisions remain understaffed, but progress has been made over the last year. Recruitment, hiring, and training of new staff remain top priorities.

In summary, ONPD agrees that new and innovative nonprescription drugs are important for improvements in self-care and public health, and potentially for health care system cost savings. We are working hard to implement historic changes to nonprescription drug regulation, including with the ACNU proposed rule, and we expect these efforts to bear fruit moving forward.

The Honorable Buddy Carter

1. **Changes by the Food and Drug Administration will for the first time allow pharmacies to dispense chemical abortion pills. An official from abortion-drug manufacturer Danco revealed that the company expects the small pharmacies that typically serve university health services or retail pharmacies on hospital campuses to adopt the FDA's change. It is important to know: What university health services or retail pharmacies on hospital campuses have already or are in the process of getting approval to dispense chemical abortion pills on campuses?**

Pharmacy certification will be managed by the drug sponsors, so we recommend reaching out to the sponsors directly for further information.

2. **Please explain why your agency did not exempt persons with previous COVID infection (aka "natural immunity") from your employee vaccine mandate and from your recommendations for mass vaccination for the population at large. Provide all data and studies relied upon at the time supporting those decisions.**

FDA implemented vaccine requirements for FDA employees in alignment with guidance provided by the Safer Federal Workforce Task Force.

The Honorable Troy Balderson

1. **Much of the public agrees that our agencies need to now return to their original, intended purposes and be proactive toward future pandemics, instead of retroactive to continue focusing on COVID-19 at the expense of the litany of other diseases and health challenges facing Americans. What changes will your agencies make in preparation for the PHE ending on May 11th? What resources and offices will continue to be dedicated to COVID-19?**

Since the start of the COVID-19 PHE declared under the PHS Act, FDA has been committed to providing timely recommendations and regulatory information to support response efforts, while at the same time continuing its other non-COVID activities.

The COVID-19 PHE declared under section 319 of the PHS Act has allowed FDA to provide important tools and flexibilities to manufacturers, health care facilities, providers, patients, and other stakeholders.

FDA will publish a notice[3] in the Federal Register addressing the Agency's COVID-19-related guidance documents,[4] including which of those guidance documents will no longer be in effect after the expiration of the PHE, and which of those guidance documents FDA is revising to temporarily continue in effect.

[3] https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19

[4] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

Importantly, the ending of the PHE declared by HHS under the PHS Act will not impact FDA's ability to authorize devices (including tests), treatments or vaccines for emergency use. Existing EUAs for products will remain in effect and the Agency may continue to issue new EUAs going forward when criteria for issuance are met.

FDA remains committed to providing notice and information to all impacted stakeholders to ensure a smooth transition.

2. **I attribute most of our country's success in the COVID-19 response to the private sector, not the government. American ingenuity allowed for us to develop vaccines, diagnostics, and therapeutics in record time. I worry that the government's many restrictions, including through the price setting sections of the Inflation Reduction Act, will hamper company's ability to innovate and prepare for the future. It has been estimated by economists from the University of Chicago that hundreds of new drugs will not come to market as a result of this policy. Patients will suffer. While I don't believe you should be in the business of dealing with reimbursement, your agency is the closest to the innovation pipeline. Do you have any mechanism to account for the lost innovation?**

The COVID-19 pandemic underscores the importance of a swift and agile response coordinated across all levels of government and, as you note, in collaboration with the private sector. Through partnerships with industry, FDA has been able to facilitate the development and availability of diverse medical products for use by patients, physicians, and health systems. We agree that this would not have been possible without industry's dedication to partnership with FDA; nor without FDA's ability to provide timely consults and regulatory flexibilities.

FDA's capacity to drive future emergency responses depends on maintaining and further building collaborations with regulatory, academic, and industry partners even in the absence of a crisis, which we are committed to continuing.

As you mentioned, FDA does not have authority over reimbursements and would defer such questions to the Centers for Medicare and Medicaid Services. However, regarding innovation, the Agency is committed to working with industry to facilitate the timely availability to patients of innovative medical products, which can in turn promote market competition and help check drug prices. The Center for Devices and Radiological Health (CDRH) has prioritized working interactively with device developers and others in the device ecosystem, including providers, patients, and payors to help achieve our vision of patient access, by streamlining the path from FDA market authorization to payor coverage and reimbursement for medical devices. The Center has developed three voluntary programs to address these issues – the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot, CDRH's Early Payor Feedback Program (EPFP), and FDA/CMS Parallel Review.

FDA knows that delay between FDA marketing authorization and coverage from payors can be challenging for small innovative medical companies, in particular, as well as patients,

particularly those with limited alternatives for diagnosing and treating potentially serious medical conditions. The Agency's goal is to help facilitate timely market availability of cleared and approved products so that patient access to such products can be achieved without unnecessary delay.

The Honorable Bob Latta

1. **Dr. Califf, over the last three years Americans have become comfortable with at-home testing for COVID. What are the prospects for OTC testing for other respiratory diseases, such as flu and RSV, either in combination with COVID or stand-alone? Other countries already have them. I can see this as a huge benefit to getting people both diagnosed and treated correctly and rapidly. What is FDA doing to encourage this evolution in at-home testing and what are, if any, the barriers?**

FDA strongly supports at-home testing for respiratory viruses, such as influenza (flu), and multi-analyte testing for flu and COVID-19. We have cleared premarket notifications (510(k)s) for central laboratory and point-of-care (POC) flu tests. We have also authorized for emergency use tests that can detect and differentiate COVID-19 and influenza at central laboratories, the POC, and over-the-counter (OTC) at-home use. Given the importance of facilitating greater consumer access to at-home testing, we are currently supportive of emergency use authorization of in vitro diagnostics (IVDs) that can detect and differentiate COVID-19 from other respiratory viruses, such as influenza.

FDA has been engaging with companies interested in developing at-home flu tests or showing that their cleared POC test still provides accurate and reliable results when used by consumers at home. Additionally, we are actively working with the National Institutes of Health (NIH) Independent Test Assessment Program (ITAP) and Rapid Acceleration of Diagnostics (RADx) to expand the availability of both POC and at-home flu and COVID-19 tests, in addition to looking at other ways to speed access to more at-home flu and COVID-19 tests. We have not and will not hesitate to move quickly to clear or authorize tests when the data are sound and the statutory standard is met, with at-home tests, including multianalyte COVID-19 tests, being a top priority for the Agency.

The Honorable Neal Dunn

1. **Why did the FDA abruptly revoke the EUAs for monoclonal antibodies without issuing prior notice to states?**

We note at the outset that FDA has not revoked EUAs for monoclonal therapies for COVID-19. However, the authorized status of these drugs and their availability for use depends on the variants in circulation at a given time and whether the products will retain activity against them. FDA has been proactive in its communications with the public regarding circulating variants and, as explained further below, attempts to the extent feasible to provide such information before changing the authorized status of the products.

The Agency's understanding of COVID-19 and its impact on public health has greatly increased since the COVID-19 PHE was declared in 2020, as has our understanding of how to treat

patients. The pathogen itself has changed and continues to change. As we have observed, the epidemiological landscape for COVID-19, specifically with emerging variants, has shifted multiple times and in a few instances, relatively quickly. In addition, the rates of infection and public health impact of the virus continues to change. Each of these factors, among others, provides a shifting clinical context against which FDA must make regulatory determinations for COVID-19 therapeutics.

Importantly, the Agency's EUAs for COVID-19 therapeutics that may be impacted by changes to SARS-CoV-2 have been intentionally proactive; facilitating the prompt assessment of the authorized products' activity against variants of concern as they are identified. Specifically, these EUAs include requirements for the EUA sponsor to monitor genomic databases for the emergence of new variants with submission of monthly reports to FDA, and to promptly test the activity of the authorized product against global variants of interest. These conditions, among others, are essential to our understanding of the therapeutics for their authorized uses, and importantly, enable FDA to promptly update the authorizations, including the authorized labeling, so providers have the most current information for clinical decision-making.

Consistent with the above, FDA, in coordination with the Administration for Strategic Preparedness and Response (ASPR), has routinely issued communications to the public providing information on emerging data associated with the monoclonal antibody therapeutics that had been available under EUA. To the extent feasible (i.e., given the rapidly shifting prevalence of circulating variants), such communications were issued in advance of any determination that the monoclonal antibody therapeutic not be authorized in the United States until further notice by the Agency. See, for example, FDA's communications beginning on February 25, 2022, regarding the EUA for sotrovimab[5], and similarly, FDA's communications beginning October 3, 2022, regarding the EUA for EVUSHELD.[6]

We also note that the EUAs for monoclonal antibody therapies, including bamlanivimab and etesevimab, administered together; REGEN-COV; sotrovimab; and EVUSHELD remain in effect; however, due to the prevalence of circulating variants that are non-susceptible to the product, and consistent with the terms and conditions of the respective authorization (i.e., limitations on the authorized use of the monoclonal antibody therapy), such therapeutics are not currently authorized for emergency use in the United States at this time. FDA remains committed to working with ASPR, the Centers for Disease Control and Prevention (CDC), and NIH on surveillance of variants that may impact the use of these therapies.

We will provide further updates and consider additional action as new information becomes available. Any updates will be made available on FDA's website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[5] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization
[6] https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us

a. Was this decision based on human efficacy data?

FDA's summary reviews supporting the Agency's decisions on EUAs for therapeutics, including the Agency's respective determination that a certain monoclonal antibody therapy not be authorized in the United States until further notice by the Agency, can be found at https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological.

b. Was there evidence of risk of the treatment?

Further information about EUAs for monoclonal therapies for COVID-19, including authorized uses, labeling, and risks can be found at https://www.fda.gov/drugs/emergency-preparedness-drugs/emergency-use-authorizations-drugs-and-non-vaccine-biological-products.

2. Does Paxlovid and Lagevrio, the two remaining authorized COVID-19 treatments, carry any risks to patients?

We note that Paxlovid and Lagevrio are not the only two treatments authorized for the treatment of COVID-19. A list of all EUAs covering COVID-19 therapeutics may be found on FDA's website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

We refer you to the authorized Fact Sheet for Health Care Providers at the link provided above for information on Paxlovid and Lagevrio, including the known and potential benefits and risks of each product associated with their authorized use.

a. Do the known benefits of these treatments outweigh the known risks?

Paxlovid and Lagevrio both remain authorized under EUA for the treatment of certain patients with mild-to-moderate COVID-19. Inherent in the Agency's decision to initially issue an EUA for these products, and continued authorization of them based on our ongoing review of the respective EUAs, is our determination, among others, that the known and potential benefits of these products, when used consistent with the terms and conditions of their individual authorizations, outweigh their known and potential risks.

3. How will the administration continue to support the development of safe treatments?

a. Can the administration provide a specific plan or timeline for when it expects to authorize or approve new safe and effective treatments?

FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (CTAP).[7] The program uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. We continue to support

[7] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

clinical trials that are testing new treatments for COVID-19 so that we gain valuable knowledge about their safety and effectiveness.

Consistent with federal statutes and FDA's implementing regulations concerning the confidentiality of commercial information and to protect the integrity of the review process, FDA generally cannot disclose information about pending applications and the status of the Agency's review of a particular drug product.[8] Therefore, the Agency is unable to provide you with updates about specific pending submissions.

4. Bivalent boosters have indicated stroke signals. Are you communicating such a risk to the public?

A preliminary signal for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent was identified, however it is unlikely to be a true clinical safety risk. The finding from the Vaccine Safety Datalink (VSD) study was reported in a joint CDC and FDA web posting on January 13, 2023 (CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older | CDC).[9] It was later presented at the January 26, 2023, Vaccines and Related Biologics Products Advisory Committee Meeting (VRBPAC) and subsequent meetings. CDC reported that the signal for ischemic stroke has attenuated, and FDA reported that they were planning a more rigorous epidemiologic study on the topic.

5. How are you further monitoring, assessing, and communicating any COVID-19 vaccine risk?

Although the totality of the data currently suggests that it is very unlikely that the preliminary stroke signal identified in the VSD study represents a true clinical risk, we believe it is important to share this information with the public, as we have in the past,[10] when one of our safety monitoring systems detects a signal. CDC and FDA will continue to evaluate additional data from the VSD and other vaccine safety systems.

It is also important to highlight that, as part of each EUA, manufacturers and vaccination providers are required to report certain information, including serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program jointly run by FDA and CDC.

COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. FDA and CDC have implemented a coordinated and overlapping approach for continuous safety monitoring of all COVID-19 vaccines using state-of the art technologies. Specifically, the Agency's monitoring

[8] Relevant law includes the Trade Secrets Act (18 U.S.C. 1905), the Federal Food, Drug, and Cosmetic Act (2 1 U.S.C. 33l(j)), and FDA regulations (21 CFR 20.6 1(c); 21 CFR 312.130(b); 21 CFR 314.430(c) and (d)(l)).
[9] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/bivalent-boosters.html
[10] https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older

following authorization or approval of the COVID-19 vaccines uses a multi-pronged approach including:

1) passive surveillance using VAERS consisting of safety reports submitted by healthcare providers (providers in the CDC COVID-19 Vaccination Program are required to report certain adverse events following COVID-19 vaccination to VAERS), patients, parents and other members of the public
2) active near real-time surveillance through CDC's Vaccine Safety Datalink, using large population-based healthcare datasets. These latter healthcare data systems offer a higher likelihood of detecting rare adverse events because they monitor medical data on millions of Americans, cover diverse subpopulations (i.e., pregnant women, the elderly, and patients with comorbidities) and can provide a longer duration of follow-up when compared to the pre-authorization or prelicensure clinical studies.

In addition, COVID-19 vaccine recipients are encouraged to enroll in CDC's V-safe After Vaccination Health Checker smartphone-based tool that uses text messaging and web surveys to check-in with vaccine recipients over time after they receive a COVID-19 vaccine. Through V-safe, vaccine recipients can quickly tell CDC if they have any side effects after getting a COVID-19 vaccine. Together, the passive and active safety surveillance provide a coordinated and overlapping approach to vaccine safety monitoring for COVID-19 vaccines.

6. Why hasn't the administration or drug manufacturers released raw patient level data of these vaccines?

a. When does the administration plan to release these data?

Before releasing these types of documents to the public, FDA, in general, must consider whether they contain confidential commercial information, personal privacy information, or other information not available for public disclosure. See, e.g., 18 U.S.C. 1905 and 5 U.S.C. 552. Further, FDA's regulations establish when information in a biological product file is held in strict confidence by the Agency and when certain data can be released to the public, for instance in response to standard processing of a request submitted under the Freedom of Information Act (FOIA). See, generally, 21 C.F.R. § 601.51. Put another way, the regulations establish when certain records may become available for public release.

7. Does the administration commit to being transparent with the American people by communicating any adverse event risks associated with the mRNA COVID-19 vaccines?

Yes, the Administration is committed to being transparent about communicating any adverse event risks associated with the mRNA COVID-19 vaccines.

a. Does the CDC believe it is important to communicate all risks associated with a medical countermeasure?

Please see CDC's responses.

b. The State of Florida recently saw a 1,700% increase in VAERS reports tied to the mRNA COVID-19 vaccines and various studies have found possible connections between the mRNA COVID-19 vaccine and several serious adverse events. Why has the CDC not communicated these risks will health care professionals and the public?

Please see CDC's responses.

The Honorable Frank Pallone, Jr.

1. I think it is important that we look back on where we started with the pandemic, and where we still need to do more work to prepare for the next public health emergency. I think all of my colleagues will remember that when the COVID-19 pandemic first exploded in our country, doctors and hospitals were facing nearly constant supply chain issues, especially for medical devices. Whether it was basic personal protective equipment like gloves, respirator masks, and gowns, or whether it was diagnostic test swabs and reagents or critical equipment like ventilators, once we addressed one challenge, another would spring up. It was obvious that our health system was not prepared for an emergency like COVID-19 from the start. FDA moved quickly and used flexible tools like the emergency use authorization and enforcement discretion policies, but even with those powers, we were clearly at a disadvantage. What tools or authorities would have been helpful to the agency in addressing supply chain issues with medical devices at the beginning of the pandemic?

Based on our experience with this pandemic, as well as with shortages and supply chain disruptions that occur outside a PHE, we believe the public health would benefit from removing the temporal limitation in section 506J of the FD&C Act that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices *during or in advance of a* PHE. The fiscal year (FY) 2023 Consolidated Appropriations Act (FY23 Omnibus) clarified FDA's authority to receive voluntary notifications from manufacturers about certain device discontinuances or disruptions, but an effective device supply chain program cannot rely solely on those manufacturers who volunteer to send information proactively. At the outset of the pandemic – prior to the enactment of section 506J – FDA reached out to more than 1,000 manufacturers of critical devices like tests, swabs, ventilators, and personal protective equipment (PPE) for information about production and supply. We received responses from fewer than one-third of the firms we contacted, and this lack of response and visibility into the supply chain hampered the government's efforts to effectively work with stakeholders to mitigate supply chain issues for these critical devices. Without this type of information, the Agency remains limited in its ability to mitigate or prevent medical device shortages that impact patients and health care providers across the United States. Supply chain disruptions that lead to shortages can result outside of a PHE. Geopolitical events, recalls, natural disasters, and closure of manufacturing facilities are all events that can lead to supply chain disruptions and shortages of critical devices, significantly impacting patient care. It is also important to note that by the time there is an emergency, it is often too late to mitigate or prevent shortages. Identifying and

mitigating supply chain vulnerabilities before they are exposed is the most prudent method for building resiliency and promoting device availability for patients.

Another important aspect of supply chain resiliency is risk management plans. The ability to require a risk management plan for critical devices would help ensure manufacturers have plans in place to enhance resiliency and mitigate future supply chain disruptions. COVID-19 showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for critical raw materials or components that are in shortage. Risk management planning that occurs outside of an emergency will help identify vulnerabilities earlier and result in greater resiliency in medical device supply chains.

There are certainly other tools and authorities that would have been helpful in responding to medical device supply chain challenges early in the pandemic, including the critical need for a modernized regulatory framework that applies to all in vitro diagnostics. The COVID-19 pandemic underscored the importance of both test access and test accuracy. Beyond COVID-19, tests are used for many different purposes and are based on many different types of technologies, and they are becoming increasingly important to our entire health care system. According to the CDC, 70 percent of health care decisions are based on clinical lab test results.[11] Some of those tests are the sole determinant of a patient's treatment. A modern regulatory framework that is specifically tailored to diagnostic tests would help to position ourselves for the future – whether it is to prepare for the next pandemic or to realize the full potential of diagnostic innovation. Such a system can balance innovation with assurance of accuracy and reliability for tests. For example, a technology certification approach could provide assurances for most tests without individual FDA review of the tests. These assurances are critical. We have seen many examples of tests that do not work – from COVID-19 tests submitted during the pandemic, to tests that are the sole determinant of which treatment a cancer patient receives. Faulty tests put patient health at risk, undermine our health care system, and hinder the country's ability to effectively address PHEs.

We look forward to continuing our work with Congress and stakeholders to strengthen our medical device supply chain authorities and to create a modern regulatory framework for all tests.

2. In the CARES Act, Congress required, during or in advance of a known public health emergency, device manufacturers report to FDA when there is a permanent discontinuance or interruption in the manufacturing of a device. Now that this requirement has been in place for almost three years, can you tell us how well it has worked? Are there any examples of FDA using this information to help address a supply chain issue?

Under the CARES Act, Congress provided FDA with critical new authority relating to device shortages codified in section 506J of the FD&C Act. As of the end of FY 2022, we had received over 455 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been in shortage. We used the information collected under these new

[11] CDC, Strengthening Clinical Laboratories, https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html#print.

authorities to help mitigate approximately 350 of the 455 shortages. FDA utilizes information provided through "506J notifications" to determine the potential for a shortage, evaluate potential impacts to patients and healthcare workers, determine appropriate mitigations, and work with our stakeholders and other U.S. government (USG) partners to implement these mitigations. Examples of FDA and other USG mitigations include:

1) priority ratings (informed by FDA assessments);
2) emergency use authorizations;
3) identification of alternatives;
4) expedited premarket reviews;
5) prioritized inspections;
6) letters to healthcare organizations, such as conservation strategies; and
7) other flexibilities, such as guidance for industry.

As an example, in late 2021 and early 2022, CDRH received 506J notifications about a shortage of blood collection tubes. FDA used this information and subsequent data gathered through outreach with the manufacturers to perform impact assessments to U.S. healthcare and patients. In response to these notifications, FDA added blood collection tubes to our public devices shortages list and subsequently implemented or informed the implementation of several mitigations that resulted in increased availability of the devices. For example, FDA worked with USG partners and suppliers of raw materials used in the production of these tubes to ensure increased allocations of these materials for the manufacturers. In addition, FDA authorized an EUA for CE-marked tubes, increasing domestic supply by approximately one million tubes per week. FDA shared best practices and issued communications to healthcare providers that included conservations strategies for existing supplies. We also worked with USG partners at the Department of Transportation and U.S. Customs and Border Protection to prioritize shipping containers with millions of blood collection tubes. This action alone resulted in over 40 million tubes being prioritized for unloading at a congested port of entry.

In late 2021, FDA was notified by a manufacturer about availability issues for saline flush syringes resulting from a manufacturer exiting the market. CDRH conducted a shortages assessment and performed extensive outreach to stakeholders. In early 2022, FDA issued an enforcement discretion letter that allowed for the import of these syringes from Europe, and we concurrently expedited review of a 510(k) submission for another device. Again, FDA provided recommendations and issued communications to healthcare providers on methods to conserve existing supply. Each of these efforts resulted in an increased availability of saline flush syringes for U.S. patients and healthcare systems, reducing patient impact.

3. In the December Omnibus bill, we clarified that outside of a public health emergency, device manufacturers may voluntarily share this information with FDA, but there is no requirement to do so. Is this voluntary reporting sufficient to avoid challenges like we faced at the beginning of the COVID-19 public health emergency?

No. The lessons of this pandemic have demonstrated that relying solely on voluntary information-sharing deprives FDA and the public of critical supply chain information. While some companies voluntarily provide this information, this is more the exception than the rule. As an example, in 2019, FDA only learned of a shortage[12] of pediatric tracheostomy tubes from patients, after the shortage had occurred because of the closure of an ethylene oxide sterilization facility. CDRH worked with the manufacturer of these tubes to locate an alternative site for sterilization. If FDA had been made aware of the potential supply chain disruption prior to the closing of this facility (e.g., a 506J notification), the Agency could have worked to help prevent or more timely mitigate the shortage that occurred. In fact, CDRH often learns about shortage of critical medical devices from patient groups and healthcare providers only after a shortage has occurred and it has become a crisis. This failure to share information, which predates the COVID-19 pandemic by years, often results in healthcare providers and patients (often our most vulnerable patient populations) not having access to the critical devices needed for their care.

Moreover, as noted in the first part of the response to Question 1, the COVID-19 pandemic demonstrated that by the time there is an emergency, it is often too late to help prevent or mitigate shortages. Supply chain disruptions were already beginning to occur even before COVID-19 cases were identified in the United States, as other nations had outbreaks and needed personal protective equipment (PPE), testing supplies, and other equipment in excess of supply. If FDA had device shortage authorities in place, we would have had visibility into supply chains, understood their vulnerabilities, and been able to apply mitigations for N-95 respirators, surgical masks, gloves, gowns, testing supplies, ventilators, and other critical devices much earlier.

The Honorable Anna G. Eshoo

1. Do you agree that the FDA Human Foods Program is chronically underfunded and understaffed?

As highlighted in the Reagan-Udall Foundation evaluation of the Human Foods Program, in inflation adjusted terms, CFSAN's budget has remained relatively flat for more than a decade despite implementing the Food Safety Modernization Act, the biggest overhaul of the Nation's food safety laws in more than 70 years. Unlike other FDA programs that receive substantial user fees to support their work, FDA's foods program relies mostly upon appropriated funding, meaning that Foods resources don't automatically adjust to increased workload like other FDA programs, which puts the Human Foods Program at a distinct disadvantage.

Importantly, our FY 2024 budget provides a historic investment to strengthen FDA's food safety and nutrition capacity – especially for infants and young children, demonstrating the

[12] https://www.fda.gov/news-events/press-announcements/statement-jeff-shuren-md-director-center-devices-and-radiological-health-agency-efforts-mitigate.

Administration's ongoing commitment to these responsibilities. The President's FY 2024 budget request includes $128.2 million in investments in food safety and nutrition modernization. The Agency welcomes the opportunity to work with Congress to strengthen this important program.

2. **The FDA oversees more than $2.5 trillion in products, accounting for almost 20 cents of every dollar spent in the U.S. Does the FDA have the capacity to manage this tremendous responsibility?**

FDA has vast responsibilities, and our highly skilled public health workforce is dedicated to executing our public health mission. We continue to look ahead at our role in public health, including at ways to modernize our efforts to keep pace with evolving science, technology, and innovation across the food and medical product fields. That's why our FY 2024 budget for FDA requests a total of $7.2 billion in annual funding. This represents an increase of $372 million in direct discretionary budget authority.

We continue to deliver on a wide range of priorities and have strategically focused our budget request to ensure our program areas have the funding they need to operate with the highest success for the good of public health. These critical investments will help us address our most urgent public health priorities, strengthen our public health capacity and business operations, advance agency-wide IT modernization capabilities, and improve our agency-wide infrastructure. Additional funding brings new ways to leverage opportunities to protect and advance the health of every American with reliable and science-based information.

We look forward to continuing our work with Congress to help meet the critical public health challenges ahead.

3. **You told the Reagan-Udall Foundation in July 2022 to "think big" in their review of the FDA Human Foods Program. Their "big" idea is to create a separate food administration within HHS. Seven former FDA commissioners recommended the same in 2019. What do you think of this recommendation**?

We believe there are significant risks and costs with creating a new, separate agency for foods. Getting a new food agency off the ground would take significant time, during which there would need to be a duplication of functions between FDA and the new agency to ensure the safety of our food system. Moreover, FDA is the oldest comprehensive consumer protection agency in the U.S. federal government. Creating a new agency from scratch runs the risk of losing the invaluable expertise and experience of FDA staff and all the lessons learned through many decades of regulating our nation's complex food system.

   a. **During a Washington Post interview in January 2023, you said you believe that the FDA is "a good place" for food safety operations to be. What about your experience as FDA Commissioner leads you to a different conclusion than seven of your predecessors?**

   During my time at FDA, I have seen firsthand that FDA has the expertise in not only outbreak response but in nutrition, laboratory science, and chemical hazards. And as discussed above, creating a standalone agency for foods raises significant concerns.

Nevertheless, we recognize that the Human Foods Program at FDA needs more attention and a better organization, and we are committed to making the structural changes necessary to enable FDA to provide better oversight of our nation's food system.

4. The Reagan-Udall Foundation report specifically calls for you to reestablish the position of Deputy Commissioner for Foods with direct line authority over all food safety programs, including the Center for Food Safety, Center for Nutrition, Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) Foods. You announced plans to redesign the Human Foods Program earlier this month, including beginning a search for a new Deputy Commissioner for Human Foods who would not have direct authority over the CVM and parts of the ORA.

A. Please provide a detailed explanation of why you decided to limit the line authority of the new Deputy Commissioner.

After careful assessment, FDA learned that the Center for Veterinary Medicine (CVM) stands best when it reports directly to the Commissioner. While CVM does have food activities that matter to the Human Foods Program, the majority of its work is in the animal drug space – such as approving innovative new products like an antibody drug to treat arthritis pain in cats. CVM's stakeholders relayed to FDA that in their view, previous structures deprioritized cutting edge animal health issues – where there is exciting and increasing innovation. However, FDA will define clear matrix organization and decision rights between CVM and the future Human Foods program where it matters for human food safety issues.

FDA has also determined the best way to deliver an effective and efficient field program is to leverage an enterprise-wide field operation that is integrated into FDA's regulatory programs (food, drugs, devices, etc.). This model will also empower the programs to set the strategic direction and resource allocation of how field resources are deployed. The regulatory programs, such as the newly envisioned Human Foods Program, will also have clear decision rights for critical activities that involve FDA's field force.

There are immense efficiencies of scale for the Agency to operate a single, global field force – devolving to multiple inspectorates would create inefficiencies and additional overhead that would not be the most efficient use of the resources Congress provides FDA. In addition, there are numerous daily operation management issues of a field force, such as ordering laboratory supplies, maintaining a fleet of vehicles, arranging travel for inspection staff, and maintaining field offices and laboratories across the nation. These daily operational management issues are best overseen by a single Agency-wide entity. FDA does not believe it would benefit the Human Foods Program or its future leader to saddle them (and other FDA programs) with this type of additional operational management responsibility.

This is also consistent with FDA's vision to move state and local food safety partnership programs into an Office of Integrated Food Safety System Partnerships under the newly

envisioned Human Foods Program. The Human Foods Program will be able to set resource allocation and strategy for FDA's cooperative programs that support state and local food safety inspections and investigations – while the daily operational work is executed by FDA's critical state and local regulatory partners. Thus, the Deputy Commissioner for Human Foods will be able to set strategic direction in a coordinated fashion over both FDA and state/local inspection operations.

B. Please respond to the criticism that this limitation perpetuates the problem of siloed programs within the food safety division of the FDA.

The proposed reorganization does address the problem of siloed programs within the food safety program and for this reason will help create a unified Human Foods Program. As discussed above, we decided to keep CVM operating as a standalone center in recognition of the diversity of work undertaken by CVM (e.g., animal drug reviews). Nevertheless, the proposed structure will allow CVM to support the Human Foods Program where its activities are relevant to human food safety. the new model for ORA, in which certain functions (e.g., state and local food safety partnership functions) will be formally combined with the Human Foods Program under one Deputy Commissioner, will enable the necessary coordinated leadership while recognizing that ORA has many other functions that don't fit within the proposed Human Foods Program structure.

5. My legislation, the DEPICT Act, passed as part of the Consolidated Appropriations Act, 2023 (Public Law 117–328) in December 2022. The legislation requires the HHS Secretary to convene a public meeting to discuss recommendations provided by the FDA to mitigate disruptions to clinical trials after the end of the Covid-19 Public Health Emergency on May 11th. When do you plan to hold this public meeting?

FDA appreciates your dedication to promoting diversity in clinical trials. As you note, the legislation requires FDA, not later than 180 days after the date on which the COVID-19 public health emergency ends, to convene a public meeting to discuss Agency recommendations during the COVID-19 public health emergency to mitigate disruption of clinical studies.

As announced in early February 2023, based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023.

We are working to comply with the legislation and expect to convene such meeting no later than 180 days from that time (November 7, 2023).