

COMPOUNDING FOR ANIMALS

ISSUE BRIEFING

EXECUTIVE SUMMARY

Since its inception in 1930, FDA has allowed pharmacists to compound medications from bulk active pharmaceutical ingredients (APIs) for non food animals, including companion, exotic, and performance animals.

However, in July 2003, FDA abruptly reversed this policy without any indication of the reasoning or justification behind the substantial policy reversal. FDA's new prohibition on compounding for non food animals will adversely affect the health and well-being of many pets and will have broad repercussions on many small businesses.

IACP has repeatedly attempted to negotiate with FDA on these policies. However, the Agency remains unmoved. FDA sent information to State Boards of Pharmacy in April 2004 announcing the initiation of an inspection campaign against pharmacies that compound for animals. Developments of this nature make this issue increasingly urgent for pharmacists and veterinarians who provide care for animal patients.

NECESSITY OF VETERINARY COMPOUNDING

IACP strongly supports the rights of pharmacists to compound for non food animals from bulk ingredients. Such compounding is part of the fundamental, historical practice of pharmacy and necessary to preserve the health and well-being of many companion, exotic, and performance animals. If pharmacists are limited to using FDA-approved, commercially available drugs, many animals will die, go untreated, or suffer needlessly.

There are many situations that may require pharmacists to compound medications from bulk ingredients for animal patients, which may include:

- 1) *Discontinued Products*: Pharmacists can compound commercial medications that have been discontinued from the market, not for reasons of safety or effectiveness, and that would otherwise be unavailable;
- 2) *Product Integrity*: Pharmacists use bulk APIs to compound medications when using a commercially available, finished product as the ingredient source could add unnecessary excipients to the medication and increase the risk of contamination (e.g. sterile medications) or yield a product which is not concentrated enough to offer proper compliance;
- 3) *No Alternative Therapy*: Pharmacists often compound medications using bulk APIs when there is no commercial alternative to treat the disease state or condition treated by the compounded medication;
- 4) *Patient Compliance*: Pharmacists also compound some medications for animal patients to make it easier for pet owners to administer medication to their pet, which often involves flavoring a medication or changing the dosage form.

FDA itself has repeatedly recognized the importance of compounding medications for animals, inasmuch as commercially available drugs significantly underserve animal patients. Pharmacists, who can customize medications based on a veterinarian's prescription to meet an animal's unique medication need, currently address this gap in medication accessibility.

However, pharmacists must have access to bulk APIs to continue meeting these needs and to prevent the unnecessary suffering and harm of animals.

REGULATORY TIMELINE

1988 and 1989

The U.S. Food and Drug Administration (FDA) has long contended that compounding for animals from bulk ingredients is illegal. This position is supported by two U.S. Court of Appeals¹ decisions: *United States v. Algon Chemical Inc.*, 879 F.2d 1154 (3d Cir. 1989) and *United States v. 9/1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988). FDA argues that these court cases affirm its position that the Federal Food Drug & Cosmetic Act of 1938 (FDCA) does not permit veterinarians to compound unapproved finished drug products from bulk ingredients, unless the finished drug is not a new animal drug. FDA extends the principle established by the court to compounding by pharmacists.

One of the courts specifically acknowledged the FDA's policy that, if the need is great and the risk small, the FDA may exercise regulatory discretion with respect to veterinarians compounding from approved drugs. For many years, FDA has exercised regulatory discretion in allowing compounding of medications from bulk ingredients for non food animals.

These two court cases are significant in that FDA cites them to support their theory that compounding from bulk drugs for animals is subject to FDA's enforcement discretion.

1994

Congress passed the Animal Medicinal Drug Use Clarification Act (AMDUCA) in October 1994 to allow and set parameters for extralabel uses of approved animal drugs and approved human drugs in animals. The AMDUCA law does not contain any specific references to compounding.

1996

FDA issued final regulations implementing AMDUCA November 1996. Section 530.13 of these regulations sets parameters for compounding from approved (finished) drugs for animals. The regulations state that the regulations "shall not be construed as permitting compounding from bulk drugs." FDA further issued a Compliance Policy Guide (CPG) in July 1996 to discuss FDA's policy on compounding from bulk drugs for animals. The CPG essentially states that in the absence of an approved new animal drug application (NADA), the compounding of a new animal drug from a bulk drug results in an adulterated new animal drug in violation of FDCA Section 501(a)(5). However, in this CPG, FDA also identified compounding from bulk drugs for non food animals as activity that "would not ordinarily be considered for regulatory action," consistent with past FDA enforcement discretion in this area.

2001

On November 2, 2001, Stephen Sundlof, Director of the Center for Veterinary Medicine (CVM) at FDA, announced to the Pharmaceutical Committee of the U.S. Animal Health Association that CVM was initiating a "crackdown" on illegal drug compounding. In this presentation, compounding from bulk ingredients was targeted as an illegal practice. The presentation explained FDA's strategy to "dry up the source of supply" of bulk drugs used to compound drugs

¹ The U.S. Court of Appeals is the highest federal court before the Supreme Court. At least one of these cases was appealed to the Supreme Court, which refused to hear the case.

for animals by curtailing imports of bulk drugs and taking enforcement action against suppliers of bulk drugs to pharmacies.

Until 2001, there were very few enforcement actions by FDA regarding compounding from bulk ingredients for animals—only a couple of cases in the 1990's of FDA enforcement action against pharmacies that were compounding for food animals. Because of the technical nature and legal risks of such compounding, IACP, in general, advised against compounding for food animals. However, FDA exercised lenient enforcement discretion on compounding from bulk ingredients for non food animals and did not initiate enforcement action against pharmacies engaging in this practice.

2002

In April 2002, the U.S. Supreme Court overturned Section 503A of the Food and Drug Administration Modernization Act of 1997 (FDAMA) due to unconstitutional advertising restrictions. Section 503A had been added as a part of FDAMA to address growing concerns about FDA's regulation of compounding. Section 503A included a recognition that compounding was legal and outlined specific parameters whereby compounding would be exempt from FDA's New Drug Applications (NDA) and Good Manufacturing Practices (GMP). It also provided for the use of bulk ingredients in compounding. FDAMA Section 503A is considered applicable to medications compounded for human patients.

In May 2002, FDA's Center for Drug Evaluation and Research (CDER) published a revised CPG on Pharmacy Compounding that outlined factors that the agency would use to distinguish between pharmacy compounding and manufacturing in the guise of compounding. IACP had a number of concerns with this guidance, which we have been actively working with CDER to resolve. CDER has announced that it will issue a revised, draft CPG for public comment during summer 2004.

2003

In July 2003, FDA's Center for Veterinary Medicine (CVM) issued a revised CPG on animal drug compounding. In this CPG, FDA reversed its policy of allowing compounding from bulk ingredients for non food animals. FDA abruptly reversed this policy without providing any justification for the change and without allowing input from affected parties. FDA issued this CPG as a final guidance, in violation of FDA's good guidance practices regulation. This is a significant policy change which has many severe and adverse implications for animal health and the viability of many small businesses.

WHY IS FDA CONCERNED ABOUT ANIMALS?

FDA's concern with compounding for animals appears to stem from complaints from pharmaceutical manufacturers over the copying of commercially available products. There seem to be more intense complaints from pharmaceutical manufacturers over the copying of commercially available animal products than human products. FDA states that they do not want to concede that some compounding from bulk pharmaceutical ingredients is acceptable because it weakens their case against the types of compounding they want to limit (i.e. large-scale copying of commercial product).

However, there are alternative, less burdensome means to limit such large-scale copying of commercial product without promulgating a CPG that eliminates all compounding from bulk

ingredients, and likewise eradicates many beneficial therapies for non food animals. IACP has written extensive comments outlining suggested revisions to the CPG and has presented FDA with these proposals on several occasions, as detailed below.

Compounding Pharmacy has had extensive past conversations with FDA's Center for Drug Evaluation and Research (CDER), the Center responsible for human drugs; yet FDA's Center for Veterinary Medicine (CVM), the Center responsible for animal drugs, has not benefited from such history. Therefore, CVM was largely ignorant of the animal patient needs involved in this issue or our willingness to resist their blanket ban on all compounding from bulk pharmaceutical ingredients. We have been presented with no evidence to suggest that pharmacy compounding has an adverse impact on non food animal health. On the contrary, there is extensive evidence demonstrating that animals have often benefited from these services.

IACP's EFFORTS TO MODIFY VET CPG

IACP has asked FDA to withdraw the CPG and reissue it in draft form to allow affected parties to comment, but FDA has not responded to this request.

Meeting with FDA CVM

IACP began negotiations with FDA during a face-to-face meeting in September 2003. During this meeting, IACP outlined a number of concerns with the revised CPG, including the new prohibition on compounding from bulk ingredients for non food animals and the procedural violations in issuance of the CPG. IACP submitted extensive written comments to FDA outlining our concerns. FDA CVM did not indicate willingness to withdraw or even revise the problematic CPG. FDA CVM instead indicated that they were unaware of any problems or complaints regarding the newly revised CPG.

Veterinarians, Pharmacists and Animal Owners Speak Up

FDA's declared lack of knowledge of the CPG's adverse impacts prompted IACP to launch a thorough, multi-pronged, grassroots effort to educate FDA on the scope of this problem. Over the past nine months, FDA has received thousands of letters from concerned pharmacists, veterinarians, and pet owners. Most ask FDA to withdraw the CPG and to reissue it in draft form to allow for affected parties to comment. Many Senators and Representatives have additionally received letters from their constituents and have subsequently contacted FDA to ask that the CPG be revised or withdrawn.

Discussions with FDA CVM Ombudsman

Receiving again no response from FDA, IACP initiated conversations with Marcia Larkin, FDA CVM Ombudsman. The Ombudsman's office probed CVM on their reasoning behind policy statements and on their method of issuing the CPG, and shared some of FDA's reasoning with IACP (see "FDA's Claims and IACP's Rebuttal"). The Ombudsman indicated that the lack of distinction between food and non food animals and other restrictive changes in this CPG stemmed from FDA's "increased concerns about compounding activity." The Ombudsman was unable to give any details or relay the specific nature of these concerns.

In early March 2004, IACP submitted a Freedom of Information Act (FOIA) request to FDA CVM asking for copies of any documents or written materials detailing the complaints on compounded medications that led CVM to have concerns with compounding for non food animals. This request should return information on any adverse events or case evidence FDA is

using to justify its drastic shift in policy regarding compounding for non food animals. We have received no response.

Small Business Administration

In addition, IACP has engaged in a number of discussions with the Small Business Administration. IACP has consulted with SBA's Office of Advocacy and SBA's Ombudsman regarding tools and strategies that may assist in our efforts to have the CPG withdrawn. IACP assisted several members in filing complaints with the SBA under the Small Business Regulatory Enforcement Fairness Act (SBREFA). SBA presented these complaints to FDA. FDA must subsequently respond to a series of SBA questions. We have not yet received FDA's response.

FDA RESPONSE TO CONCILIATION EFFORTS

In spite of IACP's numerous efforts, FDA continues to be unresponsive to requests for withdrawal and revision of its animal drug compounding CPG. In addition to being unresponsive, FDA has shown increasingly increasing inflexibility in recent communications.

FDA Letter to Compounding Stakeholder

A compounding stakeholder recently sent a letter to FDA CVM requesting withdrawal and revision of the animal drug compounding CPG, specifically requesting that the guidance be revised to permit the use of bulk active ingredients in compounding of drugs for companion and exotic animals. In his response, FDA CVM Director, Stephen Sundlof, states that CVM "do[es] not agree that the guidance should be withdrawn or modified." FDA apparently has no intention to revise the guidance, in spite of statements in the Federal Register notice and other communications that the Agency "requests comments on the guidance and will revise the document, if appropriate."

FDA Letter to Pharmacy

In addition, FDA recently sent a letter to an IACP member pharmacy that contains a number of concerning statements about veterinary compounding. Specifically, the rhetoric in the letter clearly demonstrates that FDA enforcement actions are not being confined to pharmacies whose practices emulate those of a drug manufacturer. FDA's purported concern and reasoning for issuing the CPG was to address veterinarians and pharmacists engaged in activities analogous to manufacturing. However, in terms of size and scope of practice, this pharmacy is representative of most community compounding pharmacies. Certainly the pharmacy does not fit the description of entities targeted for enforcement action. Further, the pharmacy assures FDA in the letter that it will not compound commercially available products, office stock products for veterinarians, from products withdrawn from the market for safety reasons, or use bulk ingredients to compound medications for food animals. The pharmacy also indicates that it will only compound products for non food animals upon receipt of a prescription generated in a valid veterinary-client-patient relationship. However, FDA states that these assurances "are not sufficient to bring your firm and compounded products into compliance with the Act." Under the prior animal drug compounding CPG (1996), these assurances would have been sufficient to classify the compounding as activity that "would not ordinarily be considered for regulatory action." Clearly, FDA is enforcing provisions of the new CPG against local pharmacies in ways that will be detrimental to animal health.

Further, FDA asserts in this letter that horses are considered by the Agency to be food animals. FDA writes that it "receives USDA reports of violative drug residues in the edible tissues of

horses offered for slaughter for human food for foreign markets.” This is an unreasonable assertion. First, horses are not designated as a food animal in the United States. Pharmacists compound medications for many equine performance and companion animals. Equine organizations have estimated that 15% of equine medications must be compounded. To deny treatment of these animals based on a claim that horses are a “food animal” is unreasonable and would result in unnecessary suffering and harm to this animal population. Further, withdrawal times are not required or provided on many FDA-approved, manufactured medications indicated only for use in horses. Instead, many of the drug products contain the following, approved language in the package insert, “Note: Not for use in horses intended for food.” It is absolutely unreasonable for FDA to require withdrawal times for medications compounded in a pharmacy, while not requiring this same information on manufactured products. Pharmacists must be allowed to compound products for horses with inclusion of the statement, “Note: Not for use in horses intended for food.”

FDA Communications with State Boards of Pharmacy

We are further aware that FDA has engaged in informal conversations with several State Boards of Pharmacy, encouraging state agencies to add restrictions to pharmacy laws and regulations applicable to veterinary compounding. Citing pressure from FDA, the Arkansas State Board of Pharmacy added such a stipulation to its pharmacy compounding rules in November 2003. The Texas State Board of Pharmacy also cited a pharmacy for compounding for non food animals, an unprecedented enforcement action at the state level.

Then, on April 2, 2004, FDA sent a formal letter to all State Boards of Pharmacy indicating that they will initiate an inspection campaign based on the animal drug compounding CPG. CVM requests the cooperation of the State Boards of Pharmacy in these inspections, stating:

In an effort to determine the extent of illegal veterinary compounding activities, CVM is issuing inspection assignments to FDA field offices to inspect certain pharmacies. ... Only twenty pharmacies were selected at this time due to limited resources.

The purpose of this letter is to request your Board's assistance and participation in these inspections. ... While these initial inspections may not include a pharmacy from your State, we still wanted to inform you of FDA's position on compounded veterinary drugs and to request your participation in future assignments.

IACP, in conjunction with the American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA), wrote an immediate response asking FDA to retract the letter and expressing our disagreement with FDA's actions.

This announcement showcases FDA's persistence and inflexibility on this issue. On numerous occasions FDA has been unresponsive to the pharmacy community's requests for reasonable revisions to the CPG. Rather than negotiating with affected parties to achieve productive solutions to this impasse, FDA has chosen to openly enforce a flawed policy. These pending enforcement actions will force pharmacies to discontinue all compounding for animals, which will cause unnecessary suffering and harm to many animals.

FDA CLAIMS & REBUTTAL

FDA Had an "Urgent Need" to Issue the CPG in Final Form

Myth: "This compliance policy guidance is being issued as a Level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation. It is being implemented immediately without prior public comment, because of the agency's urgent need to explain how, in light of the recent court decision and revised policy regarding drugs for human use, it intends to exercise its enforcement discretion regarding compounded drugs for animal use. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate." 68 Fed Reg. 41,591 (July 14, 2003).

IACP Response: FDA CVM argues that it implemented this CPG without prior public comment due to an "urgent need to explain how, in light of the recent court decision and revised policy regarding drugs for human use, it intends to exercise its enforcement discretion regarding compounded drugs for animal use." However, FDA responded to the *Western States* case a full 15 months after the decision was issued. Further, the *Western States* case was inapplicable to CVM policy, as FDAMA Section 503A applied only to human compounding. FDA CDER used identical reasoning (i.e. "urgent need...") when it implemented a pharmacy compounding CPG only one month after the *Western States* decision. CDER's reasoning for immediate issuance was much more compelling; yet CDER has publicly agreed to revise its CPG and issue a new guidance in draft form. Although CVM has received thousands of comments on the CPG and the above announcement indicates that it will "revise the document, if appropriate," CVM has shown no willingness to revise the guidance. Further, IACP has evidence that CVM solicited comments from one, select industry group prior to its release. This evidence certainly indicates that there was no "urgent need" and that FDA had time but chose not to solicit broad input from all affected parties prior to finalization of the guidance document.

FDA Citing Increased Concern in Policy Reversal for Non Food Animals

FDA: On a number of occasions, FDA has cited an "increased concern" over medications compounded for non food animals, especially those compounding from bulk ingredients. FDA has cited this concern in reference to the Agency's decision to alter its policy on exercising its regulatory discretion concerning compounding for non food animals.

IACP Response: IACP has repeatedly requested documentation of any concerns. IACP submitted a FOIA request asking for copies of any documents or written materials detailing the complaints on compounded medications that led CVM to have concerns with compounding for non food animals. In addition, IACP has coordinated with a number of Senators and Representatives to ask similar questions of FDA. FDA has not responded to our FOIA request and has been elusive when answering questions of this nature posed by members of Congress.

Compounded Medications Are Subject to New Animal Drug Application (NADA) Requirements

FDA: FDA has asserted on a number of occasions that "any animal drugs compounded from bulk drug substances are subject to the same approval requirements as any other animal drugs." FDA states that in the absence of an approved New Animal Drug Application (NADA) the compounding of an animal medication from a bulk drug results in an unsafe and adulterated new animal drug in violation of FDCA Section 501(a)(5).

IACP Response: IACP strongly disagrees with FDA's interpretation that compounded medications are subject to the FDCA new drug approval requirements and has an entire legal brief devoted to this subject. Compounded medications are not subject to the FDCA new drug approval process and never have been. Medication compounding by pharmacists does not constitute the manufacturing of "new drugs." Historically, while the FDA has subjected "new

drugs” to its stringent statutory requirements, pharmacists have continued the traditional compounding of drugs without interference from the FDA.

The FDCA and the processes it mandates were designed to address situations where a “new drug” would be developed over time, proved as to its safety and efficacy and then mass marketed to millions of people throughout the United States. There is an obvious conflict between the concept of a “new drug” and a compounded medication. A compounded medication is customized to meet a unique patient need, such as an allergy to a dye or ingredient, that cannot be met by a mass manufactured drug. Such medications are compounded upon receipt of a physician’s prescription and are used fairly promptly after they are formulated. Because of the limited and specific nature of compounded formulations, it would simply be impossible to subject each unique compounded medication to the rigorous “new drug” approval process that requires the investment of substantial capital and takes years to accomplish. To have applied the “new drug” requirements of FDCA to the process of compounding from 1938 forward would have been tantamount to outlawing compounding, and this, clearly, was neither intended nor occurred. It is inconceivable that Congress intended to deem all compounding to be illegal under the FDCA, and it is even more unlikely that Congress would have taken this drastic step without explicitly saying so.

Note: While IACP disagrees that compounding is subject to FDA requirements pertinent to new drugs, we are currently asking FDA to, at minimum, distinguish between compounding for food and non food animals in its CPG due to FDA’s persistent stance on compounding from bulk drugs for animals.

IMPACT ON ANIMAL OWNERS AND THEIR PETS

If FDA’s current animal drug compounding CPG is not revised and continues to be enforced, many pets will lose access to vital medications. IACP has received copies of over 1,500 letters from pet owners concerned about the impact of the CPG on their ability to obtain necessary compounded medications for their pets.

Pet owners write:

Our poodle, Prince, receives potassium bromide for severe brain seizures and would die without it. He has severe brain seizures that are uncontrollable without this medication. There is no other medication he can take or that helps him. To see him have a seizure is enough to tear your heart guts out. He suffers so severely from this condition. As I stated before, he would die without this medication!

- Brenda from Florida

My pet Pee Jei, a sharp-pei receives colchicine medication from a compounding pharmacy to treat kidney disease. Without this medication, kidneys will fail resulting in death of our beloved friend and family member. We’ve already lost three animals to kidney disease. It’s like losing a child, a best friend, and a family member all in one.

- J.W. from Arizona

Daisy, my cocker spaniel, receives hydrocortisone to treat her condition. Without this, my dog will not have her health and with an Rx that isn’t compounded she will have side effects which she doesn’t have now. She has suffered 10 years with ear pressure and a compromising immune system. After 10 years, we finally found a prescription that is

helping. Please, please do not take her health away. She's so sweet, is our baby and we've tried so hard for so many years to keep her health. Please!

- Linda from Maryland

My pet, Desi, a 12 year old cat, receives medication from a compounding pharmacy to treat ongoing bacteria in his bladder and stave off infection. My pharmacist must use bulk chemicals to make this medication for my pet. Without it, Desi would continue to have blood and bacteria in his urine and suffers bladder infections. We have struggled with this condition since June of this year and this antibacterial medication is the only thing that has worked! He is just about back to his normal, happy self since we got his condition under control through this medication.

- Barbara from Michigan

Cheshire Hull, my ferret, receives prednisolone for insulinoma and adrenal disease. She would die a slow ugly death without this medication. It is imperative that she receive this treatment. Please don't take it away from her.

- Michelle from Florida

As these testimonials demonstrate, lack of access to compounded medications would cause the unnecessary suffering, harm, and even death of many companion, exotic, and performance animals. Pet owners would suffer significant emotional distress in this process and often a loss of companionship. Exotic animal owners, especially zoos, would also suffer the loss of a tremendous capital investment. All of the suffering, loss, and death is completely unnecessary and could be easily alleviated by allowing pharmacists the continued ability to compound medications for these animals from necessary bulk ingredients.

IMPACT ON VETERINARIANS

From communications with practicing veterinarians, it is evident that veterinarians are extremely concerned with FDA's animal compounding CPG. Veterinarians are acutely aware of the impact of the CPG on their ability to properly treat the medical conditions of their patients. There are many animal patients that cannot tolerate commercial medications, due to dosing, route of administration, or compliance issues. Compounding pharmacists offer a viable solution to these problems by customizing medications to meet the individual patient's need. However, many compounded medications for non food animals require the use of bulk ingredients. Veterinarians recognize that bulk ingredients are fundamental to pharmacists' ability to meet their patients' medication needs. Likewise, IACP has received over 500 copies of letters sent from practicing veterinarians to FDA asking for withdrawal and revision of the CPG. Clearly, the services of compounding pharmacists are essential to a veterinarian's ability to properly treat his or her patients.

Further, it is our experience that state-level veterinary associations are often very supportive of their membership relative to recognizing the adverse impacts of the animal drug compounding CPG on practicing veterinarians and supporting efforts to ensure that the CPG is withdrawn and revised. IACP has worked to further engage state-level veterinary medical associations by mailing a packet of information on the animal drug compounding CPG to each state veterinary association. IACP is soliciting the support of these associations, asking each vet association to write a letter to FDA and to engage their members in a grassroots, letter writing campaign.

IACP has also engaged in a number of discussions with the American Veterinary Medical Association (AMVA) to explore collaboration on changing elements of the animal drug compounding CPG. While AVMA has indicated that it will not ask for rescission of the CPG, AVMA has also acknowledged that there are a number of problematic elements of the current CPG that should be revised. Although AVMA and IACP differ on the political strategy that should be used to change the CPG, both organizations have agreed that bulk drugs are necessary for compounding many medications for non food animals. The organizations plan to publish a consensus statement in the near future that will elaborate our agreement.

IMPACT ON PHARMACISTS

FDA's animal compounding CPG will not only preclude pharmacists from meeting the medication needs of many companion, exotic, and performance animals, it will also have a tremendous adverse affect on the business practices of many pharmacies. IACP's membership includes many pharmacies that provide compounding services only (i.e. they do not have a traditional, retail component of their pharmacy practice). Pharmacies may choose this business model to allow them to focus all their attention on providing high quality compounded medications to their patients. Further, compounding for non food animals is a significant part of most compounding pharmacy practices. In fact, there are several compounding pharmacies that specialize in providing only veterinary compounding services. The veterinary CPG, as written, will completely eliminate many compounding pharmacy practices and will have a severe impact on remaining businesses.

FDA's recent actions indicate that pharmacy owners must make a choice between losing their business or continuing to compound necessary medications for non food animals and risking FDA enforcement action. FDA has initiated this enforcement activity without having provided any analysis of the animal health or business impacts of its policy. Clearly, this activity is having a tremendous adverse impact on pharmacies and is not a workable situation.

The pharmacy community continues to reach out to FDA CVM, in spite of their continuing disregard of our overtures, and is making continued efforts toward resolution of concerns with this policy.

STRATEGY OUTLOOK

Due to FDA's hard line stance on this issue and the announcement of an enforcement campaign, this issue has become increasingly urgent in the pharmacy and veterinary communities. IACP will, likewise, increase the urgency of this issue to ensure that this CPG is withdrawn and revised.