L.D. King

From: L.D. King [redacted]
Sent: Monday, January 20, 2003 2:05 PM
To: Eilleen Fitzgerald
Subject: FW: IACP letter

-----Original Message-----
From: **L.D. King** [redacted]
Sent: **Thursday, January 16, 2003 3:08 PM**
To: **mike leake; Paul Levesque; Patsy Angelle; ray moreno; dana reed-kane**
Cc: **Jennifer Brashares**
Subject: **IACP letter**

Executive Committee:

FDA recently sent a warning letter to a large pharmacy in California citing them as a manufacturer and holding them in violation of GMP and NDA/ANDA provisions of the FDCA. While the volume and scope of this pharmacy may be disturbing, the precedence of FDA using volume, and commercial scale equipment to deem a pharmacy a manufacturer warrants a response from us. It is our understanding that the sampling and starter pack practices were discontinued upon FDA's inspection many months ago. This is one of the only warning letters to be issued to pharmacy in the post 503A era. A number of pharmacies have received a 483 or notice of findings but I am unaware of any warning letters. This pharmacy paid our attorney to write a response on behalf of IACP. It follows excerpts from FDA's warning letter. Does anyone have any concerns with sending this? Please let me know. Thanks, ld

1). You repeatedly manufacture the same inhalation products in such large quantities that the use of commercial scale equipment is required. You do not have prescription orders on hand for individually identified patients for all requests for compounded drug products that you receive.

2. The California Board of Pharmacy, in its joint inspection with FDA of December 20 and 21, 2001, determined that your firm's activities go beyond that of a pharmacy and involve manufacturing and advised your firm that the Board was referring the matter to the Attorney General's office for action with regard to your manufacturing operations. The California Board based this determination on a number of factors including, but not limited to: 1) these products are furnished to prescribers in California and other states as samples; 2) the quantity of the products manufactured by your firm is very large; and, 3) the equipment utilized by your firm to manufacture these products is commercial scale in size and style. We agree with the Board

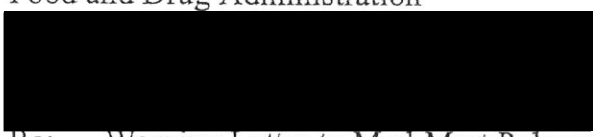
that these are characteristics that are more representative of a manufacturer rather than a retail pharmacy.

3. The California Board of Pharmacy also issued a Violation Notice to your firm on December 20, 2001, citing a lack of policies and procedures and job description for pharmacy technicians as required by pharmacy law. Your firm employs pharmacy technicians who were assigned job duties that involved the cleaning and monitoring of a complex packaging machine with no documentation of training and a lack of policies and procedures used to standardize processes and to monitor competency to ensure consumer product safety.

4. Batch records indicate that your firm produces batch sizes of [redacted] to [redacted] units, some portion of which is allotted for starter packs. A valid prescription order for identified individual patients is never received for the starter pack medications.

See the entire warning letter at http://www.fda.gov/foi/warning_letters/g3527d.htm

Mr. Russell A. Campbell
Compliance Officer
Food and Drug Administration



Re: Warning Letter to Med-Mart Pulmonary Services, No. 3003528540

Dear Mr. Campbell:

The International Academy of Compounding Pharmacists is writing with regard to the warning letter sent to Med-Mart Pulmonary Services. IACP is an international, non-profit association consisting of more than 1,800 compounding pharmacists. IACP's mission is to protect and promote the science and quality of pharmaceutical compounding. IACP takes no position regarding the specific factual issues in the warning letter, but is concerned by several policy statements in the warning letter.

IACP is concerned with FDA's apparent use of volume of compounding as a factor in determining whether a compounding pharmacy is a manufacturer. The volume of compounding should be irrelevant to determining whether a pharmacy is acting as a manufacturer. Assuming there are valid prescriptions or drug orders for each dose, the number of medications compounded is not a useful tool in distinguishing compounding pharmacies from manufacturers. Neither the former Section 503A of the Federal Food, Drug, and Cosmetic Act, nor the recently promulgated compliance policy guide considered scale of compounding as a factor in determining whether a pharmacy is acting as a manufacturer.

Moreover, specialty pharmacies often have a large prescription base because of the focus of their compounding business and their expertise in compounding particular types of drugs. By their very nature, specialty pharmacies may compound on a larger scale. We believe this to be generally a positive step forward, because those pharmacies that are expert in compounding particular drugs or types of drugs will typically develop a higher level of expertise than community pharmacies that do not

specialize. Therefore, we believe that pharmacies should not be subject to regulatory sanctions based on volume.

Second, IACP is concerned with FDA's use of scale of equipment as an indicator of whether a pharmacy is acting as a manufacturer. IACP believes pharmacists should be encouraged to use state of the art equipment, some of which may be considered to be "commercial scale." Pharmacists who use advanced technology will have an enhanced ability to properly compound safe and effective drug preparations. More pharmacists are now using automated equipment, such as automated mixing bowls and dispensing equipment, to facilitate compounding and increase the quality of compounded drugs. Particularly in light of recent developments, compounding pharmacies should be encouraged to use state of the art equipment, which can reduce manual contact with materials during the compounding, filling, and closure, reduce the amount of time consumed in the compounding process, and automate measurement and metering so as to provide for more accurate dosing. In addition, using automated equipment to generate performance data can augment management's ability to monitor the compounding process. Thus, the net effect of utilizing state-of-the-art equipment can be a significant upgrade in the consistency, reliability, and quality of a compounding operation. Objecting to the use of "commercial scale equipment" is likely to have a chilling effect on pharmacies using the most advanced technology available for fear that they will be considered a manufacturer.

Finally, we find this term to be vague and ill-defined; pharmacists are left guessing as to what is proscribed. IACP continues to believe that FDA simply should not employ either the concept or the term "commercial scale equipment" in its consideration of what distinguishes a compounding pharmacy from a manufacturer.

IACP appreciates the opportunity to express its concerns to FDA regarding the warning letter. If you have any questions, please do not hesitate to contact me.

Sincerely,

L.D. King
Executive Director, International Academy of Compounding Pharmacists

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L.D. King
Executive Director