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July 24, 2002

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam,

I attended the IACP Annual Meeting in Washington, D.C. in June when Jane Axelrad asked for comments regarding "Guidance for FDA Staff and Industry Compliance Policy Guides Section 460.200 Pharmacy Compounding".

We have studied the Guidance and wish you to consider the following comments. The intent of our comments is to allow the FDA to be able to differentiate between a manufacturer and a compounding pharmacy and still allow the compounding pharmacy to provide the best quality products they can compound.

Guidance for FDA Staff and Industry
Compliance Policy Guides
Section 460.200 Pharmacy Compounding

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"In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:"

1. "Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions."

Comments:

Some state pharmacy laws specifically allow compounding in anticipation of receiving prescriptions. (See California Code of Regulations 1716.2.)

Pharmacies are businesses. Pharmacies strive to provide good customer service. Making compounded medications available in a timely manner is both good customer service; and, oftentimes, is critical to the well-being of that patient.

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Compounded sterile injectables should be tested for the presence of endotoxin and sterility. These tests require two weeks to obtain the final results for sterility. It is not practical nor is it good therapy for a patient to bring in an urgently needed medication and then be told it will be at least two weeks before they can obtain it. The FDA guidance should take these concerns into account for compounds with a history of use and, in addition, consider that some prescriptions must be filled immediately and prior to final test results under some circumstances.

When there is a history of receiving prescriptions for a particular product, it is logical to allow anticipatory compounding in order to have the product available when the patient needs it.

Specially, this section should state:

Compounding of drugs in anticipation of receiving prescriptions except when there is a history of receiving prescriptions for a particular product. Based on past history, pharmacies may compound a limited quantity (up to a three-month quantity) in anticipation of receiving prescriptions. The pharmacy must be able to provide historical documentation to justify the quantity compounded.

2. "Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate."

Comments:

This is appropriate.

Specifically,

No changes needed.

3. "Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. S 355(i) and 21 CFR 312."

Comments:

The Food and Drug Administration Modernization Act of 1997 had a Bulk Drugs List of bulk substances permissible for use in pharmacy compounding. The list was useful and should be reinstated.

Components of "grandfathered" commercial drugs, e.g. Dexpanthenol, should be allowed.

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Components required to prepare drugs complying with any monograph in the USP should be allowed.

Specifically, this section should state:

Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. S 355(i) and 21 CFR 312., or are not components of "grandfathered" commercial drugs, or are not identified in a monograph of the USP, unless they are included on the FDA approved Bulk Drugs List.

4. "Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility."

Comments:

This is appropriate.

Specifically,

No changes needed.

5. "Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements."

Comments:

USP 24 addresses this issue well and should be a model. It is quoted below.

Specifically, this section should state:

Receiving, storing, or using drug components not guaranteed or otherwise determined to meet the following:

"A USP or an NF grade drug substance is the preferred source of ingredients for compounding all drug preparations. If that is not available, or when food, cosmetics, or other substances are used, then the use of another high quality source, such as analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade, is an option for professional judgment. For any drug substance used in compounding that is not official in the USP or NF, the pharmacist shall establish purity and safety by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source."

6. "Using commercial scale manufacturing or testing equipment for compounding drug products."



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Comments:

Pharmacies should be encouraged to use compounding and testing equipment that will result in high quality products.

Specifically, this section should state:

Using commercial scale manufacturing or testing equipment for compounding drug products for which the sole purpose is to produce large quantities of compounds for commercial sale/distribution (hence: manufacturing basis).

7. "Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale."

Comments:

This is appropriate.

Specifically,

No changes needed.

8. "Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient."

Comments:

The term "essentially" cannot be easily defined. Eliminate the term.

The Food and Drug Administration Modernization Act of 1997 was passed by Congress and stated the prescriber should be the person designating the formulation for the compounded drug. The prescriber is in the best position to designate if a variation from a commercial product is needed for his/her patient.

The only documentation needed should be the prescription for the patient.

Specifically, this section should state:

Compounding drug products that are commercially available in the marketplace.

9. "Failing to operate in conformance with applicable state law regulating the practice of pharmacy."



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Comments:

This is appropriate, but is not inclusive.

Many pharmacies send products to various states without being licensed in the various states. These pharmacies should be licensed in the states where compounded products are delivered and should abide by the laws of those states.

Specifically, this section should state:

Failing to be licensed in those states where compounded products are delivered and failing to operate in conformance with applicable state law regulating the practice.

This concludes our comments. Please do not hesitate to contact me if I can be of any further assistance.

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.


William J. Blair, Pharm. D., MBA
Director of Pharmacy Services



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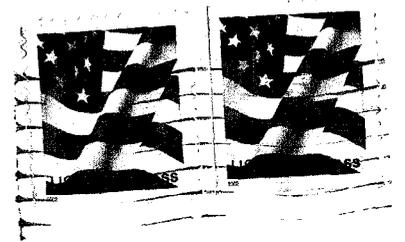
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