



February 26, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane RM 1061
Rockville, MD 20852

Re: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs
[Docket No. 2005N-0403]
RIN 0910-AA49

Dear Sir/Madam:

The following comments to Docket No. 2005N-0403 are submitted on behalf of Sepracor Inc. Sepracor is a research-based pharmaceutical company of nearly 2,500 employees with corporate headquarters located in Marlborough, Massachusetts.

Our general comments about the proposed rule are:

1. There is a potential impact on the products of private label distributors who have multiple contract manufacturers. It appears that the same product manufactured at different vendors would have different NDC numbers. This has implications on listing drugs in formularies, with hospital pharmacies, and even product identification at retail pharmacies. Each different NDC number would need to be recognized as being the same product and acceptable inventory.
2. Rather than serve the intended goal of clear identification of the source of the material, the new rule presents potential for confusion. It is important to have the product also tied to the holder of the marketing authorization. The proposed NDC scheme has little connection to the marketing authorization holder.
3. It is unclear whether currently registered establishments that are private label distributors need to take any action to withdraw their registrations.

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4. Please clarify the timeline for required implementation of the new NDC number in the commercial presentation for products whose NDC numbers must be changed to conform to the new process.

Our comments about specific provisions in the proposed rule are:

Subpart A--General

Sec. 207.1 What definitions and interpretations of terms apply to this part?

“Commercial distribution means any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or an animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of an active pharmaceutical ingredient between registered establishments within the same parent, subsidiary, and/or affiliate company.”

Comment: We urge the Agency to expand this exemption to include transfer between facilities contracted by a registered establishment or marketing authorization holder. Otherwise, products marketed by private label distributors who employ contract manufacturers are held to a higher burden of documentation than products manufactured and distributed by the same entity.

Subpart B--Registration

Sec. 207.17 Who must register?

(b) Private label distributors must not register with us unless they also manufacture, repack, relabel, or salvage drugs and are required to register under paragraph (a) of this section.

Comment: Please clarify what impact this has, if any, on private label distributors who outsource manufacturing but who perform critical GMP functions such as batch release, complaint handling, and change management.

Subpart C--National Drug Code Number

Sec. 207.33 What is the National Drug Code (NDC) number, who must obtain it, and what information must be submitted?

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(c) What information must a manufacturer submit before we will assign an NDC number to a drug? Before we assign an NDC number to a drug, the manufacturer must submit the information required under paragraphs (c)(1), (c)(2), or (c)(3) of this section. If that information changes (or as otherwise specified in paragraph (f) of this section), we will assign a new NDC number as described in paragraph (f) of this section.

(1) Assigning an NDC number to an active pharmaceutical ingredient. We will assign a unique NDC number to a drug that is an active pharmaceutical ingredient when the manufacturer provides the following information for the drug:

(iii) The package size and type; and

Comment: We encourage the Agency to allow for one NDC number per active ingredient to permit shipping in various container sizes to allow for flexibility as the application of a container that is not meant to be further broken does not apply in this situation.

(3) Assigning an NDC number to a drug manufactured for a private label distributor. We will assign a unique NDC number to a drug manufactured for a private label distributor when the manufacturer provides, in addition to the information described in paragraph (c)(1) of this section (for active pharmaceutical ingredients manufactured for a private label distributor) or paragraph (c)(2) of this section (for all other drugs manufactured for a private label distributor), the following information for the drug:

(i) The private label distributor's name, address, telephone and fax numbers, e-mail address, and labeler code;

Comment: The reference to the private label distributor's labeler code seems to contradict other parts of this proposed rule which indicate that the distributor may not request a labeler code. It is also not clear how the NDC number is requested. Please clarify.

(f) What changes in the information will require a new NDC number?

(2) In addition to the requirements in paragraph (f)(1) of this section, manufacturers must obtain a new NDC number when there is a change in an inactive ingredient for each human prescription drug that the manufacturer regards as not subject to section 505 of the act and for each animal drug that the manufacturer regards as not subject to section 512 of the act.

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Comment: The requirement for a change to the NDC number whenever an inactive ingredient changes does not seem necessary to satisfy the intent of the proposed rule and creates substantial additional work on the part of the application holder to update the number on labeling components and GMP documents. We would like the Agency to reconsider this provision.

Sec. 207.57 What are the requirements for reviewing and updating listing information?

Manufacturers, repackers, relabelers, and drug product salvagers must review and update their drug listing information required under Sec. Sec. 207.49, 207.53, 207.54, and 207.55.

(a) Manufacturers, repackers, relabelers, and drug product salvagers must provide listing information, during the annual review and update of registration information, for any drug that has not been previously listed.

Comment: Please clarify whether product made on behalf of a private label distributor at a contract manufacturer would need to be listed prior to the manufacturer's next annual update.

We thank you for this opportunity to provide comments on this proposed rule.

Sincerely,



Kathleen Grim
Executive Director, Regulatory Compliance