Proposed Rule Regarding 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


In this proposed rule, FDA proposes to reorganize, consolidate, clarify, and modify the regulations in part 207. Though much of the proposed rule is consistent with current regulations, FDA proposes several changes to current rules, the most significant of which – according to FDA – would be a requirement to use an electronic drug registration and listing system, changes to the assignment and use of National Drug Code ("NDC") numbers, changes in the regulation of private label distributors and drug salvagers, and new rules governing which registration and listing information would be available for public disclosure.

Part I of this memorandum summarizes current registration and listing requirements. Part II describes the most significant proposed changes to current requirements. Part III summarizes the other changes to the current registration and listing requirements, and Part IV describes FDA's requests for comments on a number of topics addressed in the proposed rule. Comments must be submitted to FDA by November 27, 2006.

I. Summary of Current Registration and Listing Requirements

A. Statutory Requirements

Section 510(c) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(c), requires every person upon first engaging in the "manufacture, preparation, propagation, compounding, or processing" of a drug in any establishment that he owns or operates in any State to immediately register his name, place of business, and the establishment. For purposes of this requirement, to manufacture a drug means to make the drug, using chemical, physical, or other procedures. It includes manipulation, sampling, and testing. It also includes repackaging the drug or changing the drug's container, wrapper, or labeling to further the distribution. 21 U.S.C. § 360(a)(1). The owner or operator of any establishment that engages in these activities must register its establishment on or before December 31 of each year. Id. § 360(b). The FDCA also imposes registration requirements on foreign establishments. See id. § 360(i). There are a variety of exemptions including, for example, an exemption for licensed practitioners who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice and an exemption for persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale. Id. § 360(g).

Section 510(j) governs drug listing. Every registrant must – at the time of registration – file with FDA a list of all drugs that it manufactures, prepares, or processes for commercial distribution. This listing information must be accompanied by a copy of the drug's labeling. For
prescription drugs, the registrant must also include a representative sampling of advertisements. This listing information must be updated twice a year.

Section 510(e) permits the agency to assign a registration number to any person or any establishments registered under section 510 and a listing number to each drug or class of drugs listed under section 510(j) as long as the listing number is the same as that assigned pursuant to the National Drug Code.

B. Current Regulations

Under current part 207 (21 C.F.R. part 207), with certain exceptions, owners or operators of establishments that engage in the manufacturing or processing of a drug or drugs must register their establishments and submit listing information for each of their drugs in commercial distribution, including any drug regulated under a biologic license application (BLA). A foreign drug establishment that manufactures, repacks, or relabels a drug that is imported or offered for import into the United States must also comply with the registration and listing requirements. The regulations exempt certain establishments from registration and drug listing, in accordance with the statutory exemptions in section 510(g)(1), (g)(2), and (g)(3) of the FDCA. 21 C.F.R. § 207.10.

The current regulations require, among other things, that the owner or operator of an establishment entering into the manufacturing or processing of a drug or drugs register the establishment within five days after beginning the manufacturing or processing of drugs at the establishment and submit a list of every drug in commercial distribution at that time. Id. § 207.21(a). This entity must renew its registration annually, in accordance with a specified schedule, and any change in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as an amendment to the registration within five days of the change. Id. §§ 207.21(a), 207.26. Owners and operators of registered establishments must update their drug listing information every June and December, or (at their discretion) when a change occurs. Id. § 207.21(b). The regulations describe the information required for registration and drug listing. Id. § 207.25.

FDA assigns a permanent registration number to each registered drug establishment. Id. § 207.35(a). FDA will assign a drug listing number to each drug or class of drugs using the NDC numbering system. Id. § 207.35(b). The NDC number consists of the labeler code (four or five digits), product code (three or four digits), and package code (one or two digits). Currently, FDA assigns the labeler code, and a registered establishment or distributor assigns the product code and package code within certain parameters specified by FDA. Id. The regulations request, but do not require, that the NDC number appear on all drug labels and labeling. Id. § 207.35(b)(3). If the NDC number is shown on the label, the regulations specify its format and placement. Id. If any change occurs in those product characteristics that clearly distinguish one drug product version from another (e.g., if there is a

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1 A foreign drug establishment whose drugs are imported or offered for import into the United States must comply with the establishment registration and drug listing requirements described above, unless it falls under one of exemptions described above or the drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered United States commerce. Id. § 207.40(a). No drug may be imported or offered for import into the United States unless it is both listed as required by the FDCA and regulations and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment. This restriction does not apply to a drug imported or offered for import under the investigational use provisions in parts 312 and 511 of the regulations, or to a component of a drug imported under section 801(d)(3) of the FDCA.

2 Drug products described in 21 C.F.R. § 201.25(b) must have on the label a bar code that contains, at a minimum, the appropriate NDC number in a linear bar code that meets specified standards.
change in active ingredient, dosage form, or product name), the registrant must assign a new NDC number to the new version and submit that information to FDA. *Id.* § 207.35(b)(4)(i). If a registrant discontinues a drug product, its product code may be reassigned to another drug product five years after the expiration date of the discontinued product, or, if there is no expiration date, five years after the last shipment of the discontinued product into commercial distribution. *Id.* § 207.35(b)(4)(ii).

Private label distributors that do not otherwise manufacture or process drugs are not required to register, but they must submit specified information to FDA to obtain a labeler code. 21 C.F.R. § 207.20(b). The regulations also do not require these private label distributors to list in accordance with the drug listing regulations, but these distributors may elect to submit listing information to FDA. *Id.* Private label distributors that elect to submit listing information directly to FDA assume full responsibility for compliance with the requirements of part 207. *Id.* Owners or operators of establishments that are required to register and list must submit listing information to FDA on behalf of private label distributors that do not elect to submit listing information to FDA. *Id.*

The regulations set forth eleven categories of information that, when compiled, will be available for public disclosure. *Id.* § 207.37(a)(1). These are: a list of all drug products; a list of all drug products arranged by labeled indications or pharmacological category; a list of all drug products arranged by manufacturer; a list of each drug product’s active ingredients; a list of drug products newly marketed or for which marketing is resumed; a list of drug products discontinued; labeling; advertising; information that has become a matter of public knowledge; a list of drug products containing a particular active ingredient; and a list of all code imprints. *Id.* § 207.37(a)(1). The regulation also lists the types of information that are not available for public disclosure: any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the FDCA; a list of a drug product’s inactive ingredients; and a list of drugs containing a particular inactive ingredient. *Id.* § 207.37(a)(2).

II. Significant Changes to the Current Registration and Listing Requirements

FDA is proposing many changes to the current registration and listing requirements. The most significant proposed changes to the current regulations, according to FDA, are:

A. Electronic Format

FDA would require that information be provided to the agency using its to-be-developed electronic drug registration and listing system, rather than using paper forms. Electronic submission of establishment registration and drug listing information and information required for an NDC number would generally need to comply with 21 C.F.R. part 11.

Manufacturers, repackers, relabelers, and drug product salvagers would also use this electronic system to review and update their registration and listing information. For registration information, certain changes would be reported as expedited updates (i.e., no later than 30 calendar days after the change). Other registration information would be reviewed and updated annually. Drug

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3 71 Fed. Reg. at 51314; proposed 21 C.F.R. § 207.61(a)(1).
4 *Id.* at 51294; 51312-13; proposed 21 C.F.R. §§ 207.29; 207.57.
5 *Id.* at 51294; proposed 21 C.F.R. § 207.29(a). The changes to be reported as expedited updates are: the close or sale of an establishment; any change in the name or address of an establishment; and any change in the contact information of the official contact or the United States agent.
listing information would be reviewed and updated each June and December of every year. If none of the registration or listing information has changed since the last review and update of the information, the registrant would certify electronically that no changes have occurred. (Current regulations do not require an affirmative certification in this situation.)

B. Assignment of NDC Numbers

In an attempt to address the perceived shortcomings of the NDC number system and to create an accurate, up-to-date NDC number system, FDA proposes to revise the NDC number system. Rather than assigning the labeler code and allowing the registered party to select its own product and package codes, FDA would assign all three segments. (As under current regulations, the labeler code would be either four or five digits, the product code would be either four or three digits, and the package code would be either two digits or one digit.) NDC numbers assigned to drugs before the effective date of the final rule would remain unchanged, provided the manufacturer, repacker, or relabeler, within nine months after the effective date, reviews and updates the information in FDA’s database for the NDC number. FDA would validate that current NDC numbers comply with the new regulations as finalized. The agency indicates it will work with manufacturers, repackers, and relabelers to address any problems with existing NDC numbers (such as duplicate or potentially duplicate NDC numbers) that might arise after the final rule becomes effective.

Proposed section 201.2(a) would require that the appropriate NDC number, in human-readable form and immediately preceded by the letters “NDC,” appear on the label of any drug subject to the drug listing requirements, which encompasses human drugs, including drugs regulated under a BLA and animal drugs. These drugs may be active pharmaceutical ingredients or finished dosage forms, whether prescription or over-the-counter (“OTC”). An “appropriate NDC number” is described as the NDC assigned by FDA to the last manufacturer, repacker or relabeler (including a drug product salvager who repacks or relabels the drug), or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer. This system would identify the last person responsible for the drug, which FDA explains may be important in situations in which the drug’s quality, purity, labeling, or packaging may be at issue. Under this system, a repacker would have to use its own NDC number, rather than the manufacturer’s NDC number, on drug labels. FDA specifically invites comments on this proposal. Certain trade associations have argued to FDA in the past that requiring repackers to use their own NDC numbers would be problematic and expensive.

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6 Id. at 51312-14; proposed 21 C.F.R. § 207.57.
7 Id. at 51295; 51313; proposed 21 C.F.R. §§ 207.29(b); 207.57(b)(5).
8 Id. at 51299; proposed 21 C.F.R. § 207.33(a).
9 Id. at 51296-7; 52305-6; 51345.
10 Id. at 51300.
11 Id. at 51298; proposed 21 C.F.R. § 201.2(d).
12 Id. at 51297; proposed 21 C.F.R. § 201.2.
13 Id.; proposed 21 C.F.R. § 201.2(b).
14 Id. at 51298. The National Association of Chain Drug Stores and the Healthcare Distribution Management Association asserted, in connection with the recent bar code rule (see 21 C.F.R. § 201.25), that FDA has “historically allowed the use of original manufacturer NDC numbers by repackers on the product labels of retail-based repackaged drug products” and that this practice is standard among repackers. The associations stated that mandatory use of the repackers’ NDC numbers might affect patient safety adversely and create additional, excessive costs to patients, health care providers, and payers (continued…)}
The proposed regulations also address the placement of the NDC number, requiring that it appear clearly on the drug’s label, as defined in section 201(k) of the FDCA.\(^\text{15}\)

Proposed sections 207.33(b)(1) and (b)(2) would require that manufacturers, repackers, relabelers, and in certain circumstances, drug product salvagers, obtain NDC numbers from FDA for each drug that is subject to the drug listing requirements.\(^\text{16}\) Proposed sections 207.33(c) and (d) describe the information that a manufacturer, repacker, or relabeler would be required to submit electronically before FDA assigns an NDC number to a drug.\(^\text{17}\) The information is different for each entity. This submission for the NDC number is separate from drug listing, and FDA would require the manufacturer, repacker, or relabeler to provide the information for an NDC number either before or at the time of drug listing.\(^\text{18}\) FDA also describes the changes in information that would require a new NDC number.\(^\text{19}\) In brief, the regulation would require a new NDC number for any change of information that would be required to be submitted to obtain an NDC number, except a change in certain contact information.

FDA proposes four restrictions on the use of NDC numbers. First, an NDC number could not be used to represent a drug different from the drug to which it was assigned.\(^\text{20}\) Second, a different NDC number could not be used if marketing were resumed for a drug that had been discontinued earlier.\(^\text{21}\) Third, NDC numbers could not be used to denote FDA approval.\(^\text{22}\) And, finally, NDC numbers could not be used on products that are not subject to the drug listing requirements of part 207, such as dietary supplements and medical devices.\(^\text{23}\)

The agency proposes that its electronic drug registration and listing system be used to enter and update all NDC number information, as well as registration and listing information, no later than nine months after the effective date of the final rule.\(^\text{24}\) As explained above, if a drug already has an NDC number at the time of the effective date of the final rule, the drug would retain that NDC number – provided that the manufacturer, repacker, or relabeler, within nine months after the effective date of the final rule, reviewed and updated the information in FDA’s database for the NDC number. FDA explains that to retain the NDC number, a manufacturer, repacker, or relabeler may have to provide the agency with new information about the drug’s characteristics. FDA will, if necessary, assign a new product code and/or package code, creating a new NDC number for a drug.

\(^{15}\) Id.; proposed 21 C.F.R. § 201.2(e).
\(^{16}\) Id. A drug product salvager would be required to obtain an NDC number for a drug that is subject to the drug listing requirements only if it repacks or relabels the salvaged drug. Proposed section 207.33(b)(3) states that the manufacturer, repacker, or relabeler who manufactures, repacks, or relabels a drug for a private label distributor is responsible for obtaining the NDC number from FDA for each drug that is subject to the drug listing requirements.

\(^{17}\) Id. Table 1 of the preamble to the proposed rule summarizes the information to be submitted by each entity.

\(^{18}\) Id. at 51304; proposed 21 C.F.R. § 207.33(g).

\(^{19}\) Id.; proposed 21 C.F.R. § 207.33(f).

\(^{20}\) Id. at 51305; proposed 21 C.F.R. § 207.37(a).

\(^{21}\) Id.; proposed 21 C.F.R. § 207.37(b).

\(^{22}\) Id.; proposed 21 C.F.R. § 207.37(c).

\(^{23}\) Id.; proposed 21 C.F.R. § 207.37(d).

\(^{24}\) Id.; 51345.
manufacturer, repacker, or relabeler does not review or update its information within nine months after the final rule’s effective date, FDA may assign a new NDC number to the drug or take other appropriate steps. FDA indicates that it intends to issue guidance related to these topics, assist manufacturers, repackers, and relabelers in determining whether their NDC numbers are accurate, and address any problems with existing NDC numbers.\textsuperscript{25}

FDA proposes to phase in the requirements for NDC number placement and appearance on human and animal prescription drug labels over a three-year period, beginning from the effective date of the final rule.\textsuperscript{26} For OTC labels, FDA intends to phase in the requirements over a seven-year period. The agency is considering shortening the compliance dates to two years for prescription drugs and five years for OTC drugs and invites comment on this idea.

C. Public Disclosure of Registration and Listing Information

Under proposed section 207.81(a), the following information would be made available for public disclosure upon request or at the agency’s discretion: (1) all registration information; (2) after a drug is listed, all information submitted under section 207.33 for that drug to receive an NDC number; and (3) after a drug is listed, all informed submitted under the drug listing regulations – sections 207.49 (manufacturers), 207.53 (repackers and relabelers), and 207.54 (salvagers). Certain information would be exempt: (1) the NDC number assigned to the drug immediately before the drug was received by a repacker, relabeler, or salvager,\textsuperscript{27} and (2) information submitted as the basis upon which it has been determined that the drug product is not subject to section 505 or 512 of the FDCA.\textsuperscript{28} In addition, FDA might decide on a “case-by-case basis” not to disclose information, if to do so would be “consistent with the protection of the public health and the Freedom of Information Act.” In this case, the burden would lie on the manufacturer, repacker, relabeler, or salvager to demonstrate that the information was “exempt” or its disclosure was “otherwise prohibited by law.”\textsuperscript{29}

As noted by FDA in the preamble, because proposed section 207.81 allows disclosure of information submitted under section 207.33 to obtain an NDC number, the new regulations would in some situations make available for public disclosure a drug product’s inactive ingredients.\textsuperscript{30} This information would be provided under proposed section 207.33(c)(2) and (c)(3), although the manufacturer would have the option of instead providing the approved U.S. application number. Proposed section 207.33(c)(2)(ii) would allow a manufacturer, at the time it requests an NDC number, to identify the inactive ingredients that it considers trade secret. Public disclosure of inactive ingredients not designated as trade secret at the time of listing would be authorized by the proposed regulations.\textsuperscript{31} Information identified by the applicant as trade secret, however, would not be routinely posted on the Internet. FDA would evaluate claims of trade secret protection based on the definition

\textsuperscript{25} Id. at 51305-6.
\textsuperscript{26} Id. at 51306; 51345.
\textsuperscript{27} Id. at 51320; proposed 21 C.F.R. § 207.81(a)(2). FDA proposes to exempt this information because it might disclose a business relationship between the manufacturer, repacker, relabeler, or drug product salvager and the business from which it obtained the drug, and may constitute commercial or financial information that is exempt from public disclosure under 21 C.F.R. § 20.61(c).
\textsuperscript{28} Id.; proposed 21 C.F.R. § 207.81(b).
\textsuperscript{29} Id.; proposed 21 C.F.R. § 207.81(c).
\textsuperscript{30} Id.
\textsuperscript{31} Id. at 51320-1.
of “trade secret” in section 20.61(a) of its regulations, when making disclosure decisions in response to requests made under the Freedom of Information Act.

D. Private Label Distributors and Drug Product Salvagers

Under the proposed rule, private label distributors would not be permitted to register or list. Under proposed section 207.17(b), private label distributors would not register with FDA unless they also manufacture, repack, relabel, or salvage drugs and are required to register under the FDCA or proposed section 207.17(a). Under proposed section 207.41(c), manufacturers, repackers, relabelers, and drug product salvagers would, in addition to listing their own drugs, provide all listing information to use for drugs they manufacture, repack, relabel, or salvage for private label distributors. Under the proposal, to list a drug that is manufactured, repacked, relabeled, or salvaged for a private label distributor, manufacturers, repackers, relabelers, and drug product salvagers would have to obtain any existing NDC number from the private label distributor or would have to obtain the NDC number from FDA for a drug distributed by a private label distributor and would then have to place the NDC number assigned to the private label distributor’s drug on the label. FDA requests comments on this proposed change in listing responsibilities and its potential effect on business practices.

Drug product salvagers would, in addition to registering, be required to list the drugs they salvage, even if they do not repack or relabel the drugs. Currently, drug product salvagers are required to register but not list.

III. Other Changes to the Current Registration and Listing Requirements

Other proposed changes to the current regulations include:

A. Foreign Establishments and Imported Drugs

The proposed rule would reach more foreign manufacturers, repackers, relabelers, and drug product salvagers than current regulations, because FDA proposes to revoke the exemption from establishment registration and drug listing requirements for foreign establishments whose drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered United States commerce (current 21 C.F.R. § 207.40(a)). In addition, FDA would require that all drugs imported or offered for import into the United States be listed and manufactured at a registered foreign establishment, even if the drug is imported under section 801(d)(3) of the FDCA.

B. Definitions and Interpretations of Terms

In proposed section 207.1, FDA sets forth new definitions and interpretations of terms for part 207 and revises or revokes definitions currently in section 207.3(a). In the new regulations, FDA would define: content of labeling; domestic; drug(s); establishment registration number; foreign;
importer; person who imports or offers for import; private label distributor; relabel, relabeler; and repack, repacker. A number of these terms are used in the current regulations but are not specifically defined. The proposed rule would replace the term “bulk drug substance” with “active pharmaceutical ingredient” and revise the definition to make it consistent with the definition of drug substance in current section 314.3. FDA proposes to delete the terms “advertising and labeling” and “United States agent” because the information is contained in other sections of the proposed rule. Finally, the agency proposes to revise the definitions of the terms “establishment,” “manufacturing or processing,” “material change,” “representative sampling of advertisements,” and “representative sampling of any other labeling.”

C. Registrations Requirements

Proposed section 207.17(a) would require manufacturers, repackers, relabelers, and drug product salvagers to register each establishment unless they are otherwise exempt under section 510(g) of the FDCA or proposed section 207.13. FDA would revoke the requirement in current section 207.20(a) that no owner or operator may register an establishment if any part of that establishment is registered by another owner and operator.

With respect to information required for registration, the proposed rule would revoke the requirement to include the title of each corporate officer and director. Rather than submitting the kind of ownership or operation – i.e., individually owned, partnership, or corporation – the registrant would provide, if applicable, the name of each partner, corporate officer, and director, as well as the place of incorporation. FDA is also proposing to require the name, address, telephone and fax numbers, and e-mail address of the official contact. The proposed rule would require additional information for foreign establishments.

D. Listing requirements

The proposed rule would require that each entity (i.e., manufacturers, repackers and relabelers, and drug product salvagers) submit certain information to list a drug. Most of the information that would be required from manufacturers is consistent with the information required under current regulations. Proposed section 207.49(f), however, would require that foreign

37 The proposed rule defines this term as “an agent, broker, or other entity that the foreign establishment uses to facilitate the import of its drug into the United States.” Proposed 21 C.F.R. § 207.1. In the preamble, FDA recognizes that if broadly interpreted, the word “facilitate” could be interpreted to include middlemen or other entities that may be viewed as assisting with or promoting the importation of a drug into the United States. 71 Fed. Reg. at 51289-90. A broad interpretation is somewhat limited, however, because if the foreign establishment did not know of, or have reason to know of, the middlemen, the foreign establishment would not be required to report information about the middlemen under this proposal. Id. at 51290. FDA requests comments on whether it should interpret the term “facilitate” broadly to include middlemen; on whether foreign establishments would know about such middlemen, and if so, what effect a requirement to report information about those middlemen would have on foreign establishments; and on whether there are benefits associated with such a reporting requirement, and if so, what they are. Id.

38 Id. at 51291-2; proposed 21 C.F.R. § 207.17(a).

39 Id. at 51293.

40 Id.; proposed 21 C.F.R. § 207.25(g). This information must be current, and any change in this information must be provided to FDA within thirty calendar days.

41 Id.; proposed 21 C.F.R. § 207.25(h). This information includes the contact information for the United States agent and each importer of the drug in the United States that is known to the establishment.

42 Id.; proposed 21 C.F.R. §§ 207.49; 207.53; 207.54.
establishments provide information about each importer of the drug and each person who imports or offers to import the drug to the United States, unless this information was previously provided under proposed section 207.25(h) for registration.\cite{43} For each listed drug, a repacker or relabeler would be required to submit: the NDC number; the registration number of each establishment where the repacking or relabeling is performed for the drug; for foreign establishments only, the name and contact information of each importer and of each person who imports or offers for import the drug; labeling; advertisements; and information about the private label distributor, if any.\cite{44} A drug product salvager that does not otherwise repack or relabel the drugs it salvages would be required to submit: the NDC number assigned to the drug immediately before the drug is received by the salvager; its lot number and expiration date; the registration number of each establishment where the salvager salvages the drug; for foreign establishments only, the name and contact information of each importer and of each person who imports or offers for import the drug; and information about the private label distributor, if any.\cite{45}

IV. FDA’s Requests for Comments

FDA requests comments on a variety of topics addressed in the proposed rule. Listed below are key requests for comments related to the substantive parts of the proposed rule:

- on the proposed definition of importer, including the scope of the entities included in the definition;\cite{46}

- on the proposed definition of “persons who import or offer for import”;\cite{47}

- on whether with respect to the proposed definition of “persons who import or offer for import,” FDA should interpret “facilitate” broadly to include middlemen as described in the preamble; whether foreign establishments would know about such middlemen and if so, what effect a requirement to report information about these middlemen would have on foreign establishments; and whether there are benefits associated with such a reporting requirement and if so, what they are;\cite{48}

- on requiring the label to bear the NDC number of the last manufacturer, repacker or relabeler, or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer;\cite{49}

- on the feasibility of requiring in the future that manufacturers submit the name of each inactive ingredient to obtain an NDC number for categories of drug beyond those referenced in proposed sections 207.33(c)(2)(ii) and 207.33(c)(3);\cite{50}

\begin{itemize}
\item \textsuperscript{43} Id. at 51308-10; proposed 21 C.F.R. § 207.49.
\item \textsuperscript{44} Id. at 51310-11; proposed 21 C.F.R. § 207.53.
\item \textsuperscript{45} Id. at 51311-12; proposed 21 C.F.R. § 207.54.
\item \textsuperscript{46} Id. at 51288.
\item \textsuperscript{47} Id. at 51289.
\item \textsuperscript{48} Id. at 51289-90
\item \textsuperscript{49} Id. at 51298.
\item \textsuperscript{50} Id. at 51304.
\end{itemize}
• on shortening the compliance dates by which the appropriate NDC number must appear on drug labels to two years after the effective date of a final rule for prescription drugs and five years after the effective date of a final rule for OTC drugs;\textsuperscript{51}

• on whether drug product salvagers salvage drug products for commercial distribution and whether these activities should trigger listing under the FDCA;\textsuperscript{52}

• on the proposed change and potential effect on business practices to require manufacturers, repackers, relabelers, and drug product salvagers to obtain any existing NDC number from the private label distributor or to obtain the NDC number from FDA for a drug distributed by a private label distributor and then have to place the NDC number assigned to the private label distributor’s drug on the label;\textsuperscript{53}

• on whether the agency should require manufacturers, repackers, relabelers, and drug product salvagers to provide the number of batches and batch size for each drug subject to the listing requirements;\textsuperscript{54}

• on any burden that may result from requiring that manufacturers, repackers, relabelers, and drug product salvagers affirmatively certify, when updating their registration and listing information, that no changes have occurred;\textsuperscript{55} and

• on which specific registration and listing information should be available for public disclosure.\textsuperscript{56}

If you have questions about the FDA proposal or this memorandum, please contact Erika Lietzan, Carrie Harney, or any of the other attorneys listed below.

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\textsuperscript{51} Id. at 51306.
\textsuperscript{52} Id. at 51287, 51306.
\textsuperscript{53} Id. at 51307.
\textsuperscript{54} Id. at 51312.
\textsuperscript{55} Id. at 51314.
\textsuperscript{56} Id. at 51321.
This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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