Respondents: Executive directors and key staff of faith based and community organizations that received three-year CEY grants beginning in 2007.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Lead Organization Executive Director	10	1	3.5	35
Lead Organization Key Staff	20	1	2.5	50
Partner Organization Executive Director	60	1	3.5	210
Partner Organization Key Staff	60	1	2.5	150

Estimated Total Annual Burden Hours: 445.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *OPREInfoCollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, FAX: 202–395–6974, Attn: Desk Officer for ACF.

Dated: July 2, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8–15502 Filed 7–10–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–N–0364] (formerly Docket Nos. 2006N–0466 and FDA–2007–0650)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 28, 2007 (72 FR 73589), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0614. The approval expires on June 30, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15795 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0464] (formerly Docket No. 2005N–0403)

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' This draft guidance document establishes a Pilot Program for industry to voluntarily submit drug establishment registration and drug listing information in an electronic format that FDA can process, review, and archive. The document provides guidance on what required and FDA-recommended information related to drug establishment registration and drug listing to submit and on how to electronically prepare and submit the information to FDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by September 9, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests.

The draft guidance may also be obtained by mail by calling the Office of Critical Path Programs at 301–827–1512. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0011.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA issued a proposed rule that would revise part 207 (21 CFR part 207) (hereinafter referred to as ''the 2006 proposed rule''). This rule, when finalized, will fully implement electronic drug establishment registration and drug listing. Subsequent to the publication of the proposed rule, the U.S. Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) . FDAAA amended section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) (at section 510(p)) to explicitly require the electronic submission by domestic and foreign establishments of registration and listing information (including the submission of updated information) required under section 510 of the act, unless the Secretary of Health and Human Services grants a request for a waiver if use of electronic means is not reasonable for the person requesting the waiver. FDA intends to exercise enforcement discretion and does not intend to take action to enforce this electronic submission requirement, but rather intends to pilot voluntary electronic submission during a transition period. To assist in complying with this new statutory provision, and to test FDA systems for processing such submissions, FDA is announcing a voluntary Pilot Program for electronically submitting drug establishment registration and drug listing information and the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.''

The information collected during drug establishment registration and drug listing information is fundamental to many processes FDA uses for protecting the public health, including surveillance for serious drug adverse reactions, inspection of facilities used for drug manufacturing and processing, and monitoring drug products imported into the United States. Comprehensive, complete, up-to-date information is critical for conducting these activities with efficiency and effectiveness. Electronic drug establishment registration and drug listing using computer systems to automate this process will lead to significant improvements in the timeliness and accuracy of the information over a paper-based system. This automation can be accomplished most efficiently and effectively when the information is provided in a standardized format using defined terminology.

FDA is adopting the use of extensible markup language (XML) files in a standard Structured Product Labeling (SPL)[1] format as the standard format for the exchange of drug establishment registration and drug listing information. Information in a properly created SPL file can be processed in minutes. In addition, the use of SPL files with defined terminology will facilitate the receipt of more precise and accurate information than was the case with paper submissions. Timely and accurate product information will enhance FDA's efforts to help ensure the integrity of the drug supply and protect the public health.

The draft guidance explains how to transition from submitting the required information on paper[2] to submitting the required information using the SPL standard, an electronic format that FDA can process, review, and archive. The draft guidance also describes how to voluntarily submit additional useful, but not required, information that currently is often included by industry in paper submissions. The draft guidance, along with accompanying technical documents made available on FDA's Website[3], describes how to electronically create and submit SPL files using a defined terminology for drug establishment registration and drug listing information (including labeling as specified under § 207.25) required under section 510 of the act and part 207.[4] In addition to comments on the draft guidance, FDA also is requesting comments on the adequacy and usefulness of the technical documents that are available on FDA's Web site.

With publication of the guidance, FDA is launching a voluntary Pilot Program that will enable industry to begin submitting drug establishment registration and drug listing information in electronic format. FDA plans to complete the voluntary Pilot Program and begin receiving drug establishment registration and drug listing information only electronically and in SPL format (including labeling) beginning June 1, 2009, unless a waiver is granted. Based on comments received on the draft guidance and information obtained during the voluntary Pilot Program, FDA intends to issue a final guidance before June 1, 2009.

FDA is still in the process of considering comments submitted on the 2006 proposed rule. FDA intends to revise, reissue, or revoke any final guidance as appropriate, to ensure consistency with the final rule.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the electronic submission of drug establishment registration and drug listing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets

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[1] SPL standard is a Health Level Seven, Inc., standard for the exchange of product information using extensible markup language (XML).

[2] Drug establishment registration and drug listing information is currently submitted in paper format using Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). These forms are currently available at *http://www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html*.

[3] These technical documents are currently available at *http://www.fda.gov/oc/datacouncil/spl.html*.

[4] Under section 351(j) of the Public Health Service Act, the act and regulations issued under the act apply to biological products. However, this guidance document does not apply to establishment registration and product listing information required solely under 21 CFR parts 607, 807, and 1271.

Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have a practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.

Description of Respondents: Respondents to this collection of information are foreign and domestic owners and operators of establishments that engage in the manufacture, preparation, propagation, compounding, or processing (which includes, among other things, repackaging and relabeling) of a drug or drugs[5] and that are not exempt under section 510(g) of the act or subpart B of part 207 (registrants).

A. Reporting Burden

The draft guidance describes how to electronically create and submit SPL files using defined terminology for establishment registration and drug listing information (including labeling). Most information is already required to be submitted under section 510 of the act, section 351 of the Public Health Service Act, and part 207.

Drug establishment registration and drug listing information and updates to such information, required under part 207, and certain additional recommended information are currently submitted in paper form using Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments Report of Private Label Distributors) (collectively referred to as FDA Forms; 72 FR 67733, November 30, 2007).

In addition to the information collected by the FDA Forms (72 FR 67733, November 30, 2007), the draft guidance addresses electronic submission of other required information as follows:

- For registered foreign drug establishments, the name, address, and phone number of its U.S. agent (§ 207.40(c));
- The name of each importer that is known to the establishment (the U.S. company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or is administered the drug, unless the foreign establishment ships the drug directly to the consumer or the patient) (section 510(i)(1)(A) of the act); and
- The name of each person who imports or offers for import (the name of each agent, broker, or other entity, other than a carrier, that the foreign drug establishment uses to facilitate the import of their drug into the United States) (section 510(i)(1)(A) of the act).

FDA also is recommending the voluntary submission of the following additional information, when applicable:

- To facilitate correspondence between foreign establishments and FDA, the e-mail address for the U.S. agent, and the telephone number(s) and e-mail address for the importer and person who imports or offers for import their drug;
- In providing the labeling as specified under § 207.25, for manufacturers with a Web site for voluntary reporting of adverse drug reactions, the manufacturer's telephone number and URL address that appear on the label under 21 CFR 201.57(a)(11);
- A site-specific D-U-N-S® Number[6] for each entity (e.g., the registrant, establishments, U.S. agent, importer);
- The NDC product code for the source drug that is repacked or relabeled;
- A reference drug if used as a basis for the strength of the listed drug;
- Distinctive characteristics of certain listed drugs, i.e., the flavor, the color, and image of the actual solid dosage form; and
- Registrants may indicate that they view as confidential the registrant's business relationship with an establishment, or an inactive ingredient.

In addition to the collection of information, there is additional burden for the following activities:

- Preparing a standard operating procedure (SOP) for the electronic submission of drug establishment registration and drug listing information;
- Creating the SPL file, including accessing and reviewing the technical specifications and instructional documents provided by FDA (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);
- Reviewing and selecting appropriate terms and codes used to create the SPL file (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);
- Obtaining the digital certificate used with FDA's electronic submission gateway (ESG) and uploading the SPL file for submission (accessible at *http://www.fda.gov/esg/default.htm*); and
- Requests for waivers from the electronic submission process as described in the draft guidance.

B. Burden Estimates

Reporting Burden—The estimates for the number of respondents, annual frequency per response, and total annual responses indicated in table 1 of this document are based on our current estimates of the number of registrants and the number of submissions using the FDA Forms (OMB Control No. 0910–0045). FDA estimates that it would take an additional 2 hours per response (in addition to the estimated 2.5 hours per

[5] Means both human, including biological products, and animal drugs.

[6] A D&B® D-U-N-S® Number is a unique nine-digit sequence recognized as the universal standard for identifying and keeping track of over 100 million business worldwide. Submitting the site-specific D-U-N-S® Number for an entity would provide by reference to the number certain business information for that entity, e.g., address, parentage.

response for registering, labeler code requests, listing, and providing updates to the information approved under OMB Control No. 0910–0045) for the collection of information not currently submitted using the FDA Forms, and to create and upload the SPL file. FDA anticipates that the hours per response will decrease over time due to the flexibility of submitting information for registering multiple establishments or listing multiple drugs in one SPL file instead of submitting individual FDA Forms, and increasing familiarity with the use of the standards and terminology for creating the SPL file.

In certain cases, if it is unreasonable to expect a person to submit registration and listing information electronically, FDA may grant a waiver from the electronic format requirement. Because registrants will only need a computer and access to the Internet, FDA envisions few instances in which electronic submission of registration and listing information will not be reasonable for the person requesting the waiver and, thus, is estimating that FDA would grant one waiver annually. We estimate that a one-time burden for requesting a waiver would be an hour of time for a mid-level manager to draft, approve, and mail a letter.

Recordkeeping Burden—In table 2 of this document, FDA estimates that 3,295 (39 + 3,256) respondents would expend a one-time burden of approximately 40 hours in preparing, reviewing, and approving an SOP for creating and uploading the SPL file; and an estimated 1 hour annually to maintain the SOP as needed.

FDA estimates the information collection burden, in addition to that approved under OMB Control No. 0910–0045 as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New registrations, including new labeler code requests	39	14.72	574	2	1,148
Annual updates of registration information	3,256	2.99	9,735	2	19,470
New drug listings	1,567	6.57	10,295	2	20,590
New listings for private label distributors	146	10.06	1,469	2	2,938
June and December updates of all drug listing information	1,677	11.21	18,799	2	37,598
Waiver requests	1	1	1	1	1
Total					81,745

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
One-time preparation of SOP	3,295	1	3,295	40	131,800
SOP maintenance	3,295	1	3,295	1	3,295
Total					135,095

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

C. Costs Associated with Electronic Submission

There are no capital costs or operating and maintenance costs associated with the transition from paper to electronic submissions. To create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's Electronic Submission Gateway (ESG).

Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and Internet are usually available at public facilities, e.g., a community library; or they may request a waiver from submitting the information electronically.

Software is necessary to create a ''document.'' The SPL file or ''document'' may be created internally by a business with experience with SPL, or a business may use a user-friendly software (XForms)[7] available at no cost for industry use. In addition to the software, FDA also provides technical assistance, and other resources, terminology, and data standards regarding SPL files.[8]

Once the SPL file is created, the registrant would upload the file through the ESG. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. However, a small fee of up to $20.00 is charged for the digital certificate and the registrant may need to renew the

[7] See *http://www.fda.gov/oc/datacouncil/xforms.html.*

[8] See *http://www.fda.gov/oc/datacouncil/spl.html.*

certificate not less than annually. FDA is not calculating this small fee as cost of doing business because it is less than or equal to the biannual courier costs the registrant incurs for paper submissions.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/cvm/guidance/guidance.html*, and *http://www.regulations.gov*.

Dated: July 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15801 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0372]

Global Harmonization Task Force, Study Groups 1 and 5; Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of final and proposed documents that have been prepared by Study Groups 1 and 5 of the Global Harmonization Task Force (GHTF), respectively. These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe FDA's current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

DATES: Submit written or electronic comments on these documents by October 9, 2008. After October 9, 2008, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of these documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the documents.

Submit written comments concerning these documents to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.reguations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For information regarding Study Group 1:Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation,Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration,9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

For information regarding Study Group 5:Herbert P. Lerner, GHTF, Study Group 5, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3641.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice relates to documents that have been developed by two of the Study Groups (1 and 5).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidelines that could help lead to harmonization. As a result of its efforts, this group has developed final document SG1/N44:2008. SG1/N44:2008 (final document) entitled ''Role of Standards'' provides information on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating that the device conforms to relevant essential safety and performance criteria.

Study Group 5 was initially tasked with the responsibility of developing documents on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. As a result of its efforts, this group has developed proposed document SG5(PD)/N37:2007. The proposed document SG5(PD)/N37:2007 entitled ''Clinical Investigations'' introduces general principles of clinical investigations of medical devices and general principles when considering the need for a clinical investigation of a medical device. This document primarily addresses the use of clinical investigations to support a marketing authorization application.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions. In particular, FDA seeks comments on the