office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Lori A. Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993, 301–796–0210; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' This document offers specific guidance to industry and FDA staff on the content and format of DHCP letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

In the **Federal Register** of November 12, 2010 (75 FR 69449), FDA announced the availability of a draft guidance for industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' The notice gave interested persons an opportunity to comment by January 11, 2011. The Agency received several comments from health care providers, firms, and other groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified information in the guidance in response to the comments or on our own initiative. This guidance finalizes the draft guidance issued in November 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0754.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov*.

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01305 Filed 1–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0032]

Improving the Quality of Abbreviated New Drug Application Submissions to the Food and Drug Administration; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to receive input and suggestions from the public on ways to improve the quality of abbreviated new drug applications (ANDAs) and associated amendments and supplements to FDA's Office of Generic Drugs (OGD). Specifically, FDA is interested in hearing about any difficulties sponsors are having developing and preparing their ANDA submissions that FDA could help address, for example by providing more or better information to industry. This action is intended to solicit suggestions that will improve the completeness and quality of ANDA submissions to FDA. FDA is also seeking input on how to best share suggestions for improving the quality of ANDAs with the generic drug industry. More complete, higher quality ANDA submissions will positively affect the availability of low-cost, high-quality generic drugs to the public.

DATES: Although FDA welcomes comments at any time, to help FDA address issues related to ANDA submission quality in a timely fashion, we encourage submission of electronic or written comments by March 24, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519

Standish Pl., Rockville, MD 20885, 240–276–8607, *elizabeth.giaquinto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed the Generic Drug User Fee Amendments (GDUFA) (Pub. L. 112–144, Title III) into law. With the enactment of GDUFA, OGD committed to expedite the availability of high-quality, lower cost generic drugs by bringing greater predictability to the review times for ANDAs and associated amendments and supplements. OGD agreed to specific performance review metrics to reduce the time needed to bring a generic drug to market compared to typical pre-GDUFA review times. However, OGD's review is often hindered by the quality of the ANDA submissions.

As part of efforts to fulfill its GDUFA commitments, OGD is soliciting input and suggestions from all interested stakeholders on how to improve the completeness and quality of ANDA submissions to OGD. FDA is interested in hearing about any difficulties sponsors are having developing and preparing their applications for submission that FDA could help address (please see specific questions for comment listed in this section of the document). FDA is also seeking input on how to best share suggestions for improving the quality of ANDA submissions with industry. To receive comments and suggestions from the public, FDA is establishing a public docket. Improving the quality of ANDA submissions will result in more submissions accepted for filing, fewer amendments, and easily correctable deficiencies, and ultimately, more generic drug approvals.

FDA review staff routinely note common, recurring deficiencies found in ANDA submissions to OGD and try to communicate these deficiencies to industry in guidance documents and during presentations. Common, recurring deficiencies include, but are not limited to:

- *Filing:* Failure to provide a completed Form FDA 356h; unjustified inactive ingredient levels; inadequate dissolution data; packaging less than the recommended threshold amount without justification; inadequate or insufficient stability data; submissions of non-qualitative and non-quantitative (not Q/Q) same formulations; electronic submission and formatting deficiencies; applications containing an incorrect or unfounded basis of submission.
- *Chemistry:* Poor or inadequate justification of impurities limits; failure to provide a list of potential impurities and their origins; failure to provide adequate verification of analytical procedures for active pharmaceutical ingredient and finished dosage forms, where appropriate; failure to identify the critical manufacturing process parameters or to link in-process controls to development studies; failure to provide appropriate acceptance criteria of manufacturing yields for the critical steps, or providing yield values varying without adequate rationale or explanation.
- *Sterility assurance for sterile drug product applications manufactured by aseptic processing:* Failure to describe sterilization and/or depyrogenation of relevant equipment and components that may come in contact with the sterile drug; failure to provide relevant validation data for sterilization and/or depyrogenation of relevant equipment and components that may come in contact with the sterile drug; failure to provide validation data for sterilizing grade filters, if needed; failure to provide process simulation data for the proposed aseptic filling process/line/room.
- *Bioequivalence:* Inaccurate and/or incomplete information contained in electronic tables; submission of pharmacokinetic repeats; inaccurate and/or incomplete biowaiver requests (e.g., inappropriate method of solubility determination, lack of dissolution data for all strengths, missing standard operating procedures for analytical methods).
- *Fatal flaws:* Significant flaws in the design of a drug product such that the proposed product will not be able to meet all conditions of use of the reference listed drug.
- *Drug master files:* Submission contains more than a single drug substance or more than a single drug manufacturing process; failure to update the drug master file following a large number of amendments or time lapse since the original submission; failure to provide a complete description of manufacturing process and controls; failure to justify appropriate starting materials.

As noted previously, this list provides examples of common, recurring deficiencies FDA has identified. FDA is particularly interested to learn what steps it can take to help reduce these deficiencies and enhance the completeness and quality of ANDA submissions. Comments submitted to this docket are encouraged to address one or more of the following points, as well as any others that the commenter thinks are important:

1. What aspects of the ANDA application process are confusing or not well defined?
2. What problems do ANDA applicants encounter when developing a submission that FDA could help address?
3. Prior to GDUFA, were ANDA submissions consistently slowed or stalled at certain recurring review points post-filing? If so, why?
4. How should FDA share suggestions for improving ANDA submissions with industry, beyond issuing regulatory guidance?

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: *January 16, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Society of Clinical Research Associates—Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SoCRA). The public workshop regarding FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA, and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and