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.

[FR Doc. 2014–01309 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–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

clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process including the informed consent documents, regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, of IRBs, and of research sponsors.

Date and Time: The public workshop will be held on March 12 and 13, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hyatt Regency Newport Beach Hotel, 1107 Jamboree Rd., Newport Beach, CA 92660, 949–729–6061. Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $152.00 plus applicable taxes (available until February 18, 2014, or until the SoCRA room block is filled).

Contact: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *SoCRAmail@aol.com,* Web site: *www.socra.org.*

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of registration is as follows:

SoCRA member	$575
SoCRA nonmember (includes membership).	$650
Federal Government SoCRA member.	$450
Federal Government SoCRA nonmember.	$525
FDA Employee	Fee Waived

If you need special accommodations due to a disability, please contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: *SoCRAmail@aol.com* at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to ''SoCRA''. Mail to: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914. To register via the Internet, go to: *http://www.socra.org/html/FDA_Conference.htm.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: *SoCRAmail@aol.com.*

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the safety and effectiveness of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

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]

Risk Communication Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Risk Communication Advisory Committee scheduled for February 3 and 4, 2014. The meeting was announced in the **Federal Register** of January 3, 2014 (79 FR 398). The meeting is postponed due to unavoidable operational changes. Future meeting dates will be announced in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, Silver Spring, MD 20993, 240–402–5274, or email: *RCAC@fda.hhs.gov* or FDA Advisory Committee Information