I. Background

FDA is announcing the availability of a guidance for industry entitled ''Residual Drug in Transdermal and Related Drug Delivery Systems.'' This guidance provides recommendations to developers and manufacturers of TDDS, TMDS, and topical patch products regarding use of an appropriate scientific approach during product design and development—as well as during manufacturing and product life-cycle management—to ensure that the amount of residual drug substance at the end of the labeled use period is minimized. In the **Federal Register** of August 3, 2010 (75 FR 45640), FDA announced the availability of the draft version of this guidance. The public comment period closed on November 1, 2010. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

Existing TDDS, TMDS, and topical patches contain a larger amount of the drug substance than what is intended to be delivered to the patient. This excess amount of drug substance is needed to facilitate delivery of the intended amount of the drug to the patient and remains as residual drug in the used system. The amount of residual drug substance in TDDS, TMDS, and topical patches has a significant potential to impact the products' quality, efficacy, and safety (including abuse potential). Consequently, it is necessary to ensure that an appropriate scientific approach is used to design and develop these products. The approach should ensure that the amount of residual drug substance is minimized consistent with the current state of technology.

Currently marketed TDDS, TMDS, and topical patches may retain 10 to 95 percent of the initial total amount of drug as the residual drug after the intended use period. This raises a potential safety issue not only to the patient, but also to others, including family members, caregivers, children, and pets. For example, adverse events due to a patient's failure to remove TDDS at the end of the intended use period have been reported and are generally related to an increased or prolonged pharmacological effect of the drug. Also, some children have died from inadvertent exposure to discarded TDDS. Reported adverse events resulting from various quality problems pertaining to TDDS have lead to product recalls, withdrawals, and public health advisories.

To reduce some of these risks, the Agency recommends that a robust design and development approach be considered when developing and manufacturing TDDS, TMDS, and topical patches. One example of such an approach is quality by design, as described in the International Conference on Harmonization guidance for industry entitled ''Q8(R2) Pharmaceutical Development.'' The Agency also recommends that sufficient scientific justification to support the amount of residual drug in TDDS, TMDS, or topical patches be included in an application. The justification should include an evaluation of the safety risks involved with the formulation and system design, as well as support the amount of drug load in the TDDS, TMDS, or topical patch based on the proposed quality target product profile and formulation studies. Most important, the justification for applications of products with known safety issues—such as those with fentanyl-containing liquid reservoir systems—should demonstrate that the safety risk factors have been adequately mitigated.

In all cases, the level of information in the justification should be sufficient to demonstrate product and process understanding and ensure that a scientific, risk-based approach has been taken to minimize the amount of residual drug in a system after use to the lowest possible level. It is expected that the amount of residual drug in a newly developed system (including new generic drug products) will not exceed that of similar FDA-approved products.

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 residual drug in transdermal and related drug delivery systems. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). Information in an application on the product and process development and justification for the final formulation and system design is approved under OMB control numbers 0910–0001 and 0910–0014.

IV. Electronic Access

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

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20852 Filed 8–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reorganized the Center for Drug Evaluation and Research (CDER) by establishing four new Divisions under the Office of Generic Drugs. This reorganization includes the organization and their substructure components as listed in this document. This document is announcing the availability of the Staff Manual Guide that explains the details of this reorganization.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 1919 Rockville Pike, Rm. 324, Rockville, MD 20852, 301–796–4422.

SUPPLEMENTARY INFORMATION:

I. Summary

The Statement of Organization, Functions, and Delegations of Authority

for CDER (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; and 76 FR 19376, April 7, 2011) is amended to reflect the restructuring of CDER that was approved by the Secretary of Health and Human Services on May 25, 2011. This reorganization is explained in Staff Manual Guide 1264.31, 1264.36, 1264.37, 1264.38, and 1264.39, and includes the establishment of the Division of Bioequivalence II, Division of Microbiology, Division of Clinical Review, and Division of Chemistry IV. In addition, CDER is retitling the Division of Bioequivalence to the Division of Bioequivalence I.

II. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of Food and Drugs or the Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Person interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20859 Filed 8–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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) Philadelphia District Office, in co-sponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop on 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 (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRB, and research sponsors.

Date and Time: The public workshop will be held on November 16 and 17, 2011, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Philadelphia City Center Hotel, 201 North 17th St., Philadelphia, PA 19103, 1–215–448–2000.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $159 plus applicable taxes (available until November 1, 2011, or until the SoCRA room block is filled).

Contact: Anne Johnson, Food and Drug Administration, Philadelphia District, 900 U.S. Customhouse, Second & Chestnut Streets, Philadelphia, PA 19106, 215–597–4390, FAX: 215–597–4660, e-mail: *anne.johnson@fda.hhs.gov*; or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., suite 109, Chalfont, PA 18914, 1–800–762–7292 or 215–822–8644, FAX: 215–822–8633, e-mail: *SoCRAmail@aol.com,* Web site: *http://www.SoCRA.org.* (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 publishes in the **Federal Register**.)

Registration: The registration fee covers the cost of 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:

COST OF REGISTRATION

SoCRA member	($575.00)
SoCRA nonmember (includes membership)	($650.00)
Federal Government member	($450.00)
Federal Government nonmember	($525.00)
FDA Employee	(free) Fee Waived

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this educational activity for a maximum of 13.3 Continuing Education Credits for SoCRA CE and Nurse CNE. SOCRA designates this live activity for a maximum of 13.3 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation. CME 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 continuing nursing education 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 e-mail, along with a check or money order payable to ''SoCRA''. Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see *Contacts*).