ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7864.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for clinical investigators, sponsors, and IRBs entitled ''Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting—Improving Human Subject Protection.'' Under the regulations in 21 CFR part 50 (Protection of Human Subjects), part 56 (21 CFR part 56) (Institutional Review Boards), part 312 (21 CFR part 312) (Investigational New Drug Application), and part 812 (21 CFR part 812) (Investigational Device Exemptions), an IRB must review and approve a clinical study before the study is initiated. Additionally, after an IRB's initial review and approval, an IRB must conduct continuing review of the study at intervals appropriate to the degree of risk presented by the study, at least annually. The primary purpose of both the initial review of a study and the periodic review of the conduct of the study is to assure the protection of the rights and welfare of human subjects. To assure the protection of the rights and welfare of human subjects during the conduct of a clinical study, an IRB must have information concerning unanticipated problems in the study and changes in the research activity. Such information may be important to the IRB's review. This draft guidance discusses adverse event reporting to IRBs by sponsors, and investigators, and emphasizes the greater value of well-analyzed adverse event data to an IRBs review. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on adverse event reporting for the purpose of improving human subject protection. 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. The Paperwork Reduction Act of 1995

This draft 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). The collections of information in part 56 have been approved under OMB Control No. 0910–0130; the collections of information in part 312 have been approved under OMB Control No. 0910–0014; and the collections of information in part 812 have been approved under OMB Control No. 0910–0078.

III. 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 paper 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6595 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0117]

Draft Guidance for Industry on Orally Disintegrating Tablets; 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 ''Orally Disintegrating Tablets.'' The draft guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an orally disintegrating tablet (ODT) and also provides recommendations to applicants who would like to designate a proposed product as an ODT.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frank O. Holcombe, Jr., Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Orally Disintegrating Tablets.'' The draft guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an ODT and also provides recommendations to applicants who would like to designate proposed products as ODTs.

In an effort to develop drug products that are more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations, pharmaceutical manufacturers have developed products that can be ingested simply by placing them on the tongue. The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need for chewing the tablet, swallowing an intact tablet, or taking the tablet with water. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

As firms started developing additional products using different technology and formulations, many of these later products exhibited wide variation in product characteristics from the initial products. Because this shift in product characteristics can affect a product's suitability for particular uses, the agency developed this guidance for industry.

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 orally disintegrating tablets. 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 paper 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 30, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6509 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: April 30, 2007, 8:30 a.m.– 5 p.m.; and May 1, 2007, 8:30 a.m.–2:30 p.m.

Place: Hilton Washington, DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852–1699.

Status: The meeting will be open to the public.

Agenda: The agenda for April 30 in the morning will include: Welcome and opening comments from the Chair and Executive Secretary of COGME and senior management staff of the Health Resources and Services Administration.

On April 30, following the welcoming remarks from the COGME Chair, the Executive Secretary of COGME, and Agency senior management, there will be a review and discussion of the draft paper ''Enhancing GME Flexibility,'' by Barbara Chang, M.D., and other writing group members. After lunch there will be a review and discussion of the draft paper ''New Paradigms for Physician Training for Improving Access to Healthcare'' by Earl Reisdorff, M.D. and other writing group members. At 3 p.m. there will be a breakout of Council members into the two draft writing groups for further report revisions.

On May 1 there will be reports to the Council and further discussion on writing group activities and reports. The Council will conclude with a discussion of the timeframe and next steps for producing the Reports.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6785.

Dated: April 2, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–6597 Filed 4–6–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Proposed Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for Public Comment.

SUMMARY: HRSA is soliciting comments on the proposed eligibility criteria for the *Reimbursement of Travel and Subsistence Expenses toward Living Organ Donations* Program. Eligibility criteria were proposed by the program grantee, the Regents of the University of Michigan, to HRSA. HRSA has determined that the proposed eligibility criteria constitute a proper interpretation of the authorizing statute's requirements, including determinations as to which individuals would otherwise be unable to meet the eligible expenses authorized under this Program. HRSA is soliciting public comment on the criteria outlined in this notice. HRSA will consider the comments in light of the authorizing statute and seek feedback from the Regents of the University of Michigan concerning the comments. HRSA will then approve final criteria. The final program eligibility criteria will be posted on the Reimbursement of Travel and Subsistence Expenses for Living Organ Donation Web site, *http://www.livingdonorassistance.org*.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before May 24, 2007.

ADDRESSES: Please send all written comments to James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 12C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Congress has provided specific authority under