

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on orally disintegrating tablets.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.

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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]

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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