the maximum permitted energy level of X-rays for treating food to 7.5 million electron volts (MeV) from the currently permitted maximum level of 5.0 MeV.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3423.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 3M4745) has been filed by Ion Beam Applications, 6000 Poplar Ave., suite 426, Memphis, TN. The petition proposes to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) by increasing the maximum permitted energy level of X-rays for treating food to 7.5 MeV from the currently permitted maximum level of 5.0 MeV.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 24, 2003.

Alan M. Rulis,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03–5955 Filed 3–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0043]

Guidance for Industry on Integration of Dose-Counting Mechanisms into Metered-Dose Inhaler Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using metered-dose inhalers (MDIs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 guidance to the Dockets Management Branch (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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sandy Barnes, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, rm. 8B–45, Rockville, MD 20857, 301–827–1055.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using MDIs. The guidance reflects the agency's current recommendations regarding the integration of dose-counting mechanisms into MDI drug products for oral inhalation. Although the contents of the guidance should be considered by any manufacturer of any MDI drug product (including nasal MDI products), this guidance is neither specifically intended for manufacturers of already marketed MDI drug products for oral inhalation nor for manufacturers developing MDIs for other routes of administration (e.g., nasal MDIs). It is also not intended for manufacturers developing multidose dry powder inhalers (MDPIs), which already incorporate dose counters as an integral part of the delivery system. Manufacturers developing new MDPIs are encouraged to continue including dose counters in their delivery systems and may find the contents of this guidance useful in their planning.

A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of December 11, 2001 (66 FR 64045). This guidance contains only clarifying editorial changes.

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 integrating dose-counting mechanisms into MDI drug products. 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, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch 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 5, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–5956 Filed 3–12–03; 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).

Date and Time: April 10, 2003; 8:30 a.m.—4:30 p.m. April 11, 2003; 8:30 a.m.—12 noon.

Place: Holiday Inn Select, Versailles 4, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Status: The meeting will be open to the public.

Agenda: The agenda for April 10 will include: welcome and opening comments