its product. Although the pharmaceutical agreements that the Commission has challenged to date have involved cash payments, a company could easily evade a prohibition on such agreements by substituting other things of value for cash payments. Thus, to protect against a recurrent violation, the proposed order is not limited to cash payments.

The proposed order would create two exceptions to Paragraph XII's ban on giving value for delayed entry. First, the ban would not apply if the value BMS provided to the ANDA filer was only: (1) The right to market the ANDA product prior to expiration of the patent that it is alleged to infringe; and/or (2) an amount representing BMS's expected future litigation costs, up to a maximum of two million dollars. This exception reflects that a payment limited to the NDA-holder's expected future litigation costs is not likely to result in a later generic entry date than would be expected to occur absent the payment. As a fencing-in provision, the proposed order sets a two-million dollar limit on expected litigation cost payments. In addition, the exception requires that BMS notify the Commission at least 30 days in advance of consummating such an agreement, to allow an assessment of potential harm to competition that could arise as a result of the exclusivity provisions of the Hatch-Waxman Act. Paragraph XVI sets forth a notification process similar to that used for mergers under the Hart-Scott-Rodino Act, which is designed to permit the Commission to obtain additional information when an agreement's potential effect on the triggering of the 180-day exclusivity period may raise competitive concerns.

A second exception addresses the possibility that there might be some agreements that fall within the terms of the prohibition in Paragraph XII that the Commission would not wish to prohibit. Thus, the proposed order includes a mechanism that would permit the Commission to consider and permit such arrangements.

Paragraph XIII prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The complaint alleges that BMS's settlement agreement with Schein not only barred sale of the ANDA product, but also prohibited marketing of any other generic version of BuSpar, regardless of whether it infringed a BMS patent.

The proposed order would also ban agreements in which a first ANDA filer agrees not to relinquish its right to the 180-day exclusivity period provided under Hatch-Waxman (Paragraph XIV). Under a proviso, however, such agreements are permitted in the context of a licensing arrangement if: (1) The first ANDA filer comes to market immediately with a generic version of the reference drug product; (2) the ANDA filer either triggers or relinquishes the 180-day exclusivity period; and (3) BMS complies with the notice requirements of Paragraph XVI. Although a ban on relinquishing exclusivity rights was not part of the challenged settlement agreement between BMS and Schein, such agreements have been used to thwart generic entry and the prohibition of such agreements will help to prevent future unlawful conduct.[21]

Paragraph XV bars agreements that involve payment to an ANDA filer and in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. As with Paragraph XII's treatment of final settlements, it extends beyond cash payments to cover the NDA holder's providing ''anything of value'' to the ANDA filer. The proposed order also provides for an exception to the provision on interim settlements if BMS presents the agreement to a court in connection with a joint stipulation for a preliminary injunction, and the following conditions are met:

- BMS must provide certain information to the Commission at least 30 days before submitting the joint stipulation to the court, and must also provide certain information to the court along with the joint stipulation;
- BMS may not oppose Commission participation in the court's consideration of the request for preliminary injunction; and
- Either: (1) The court issues a preliminary injunction and the parties' agreement conforms to the court's order; or (2) the Commission determines that the agreement does not raise issues under Section 5 of the FTC Act.

Notice and Compliance Provisions

The form and timing of the notice that BMS must provide to the Commission under Paragraphs X, XII, XIV, and XV of the proposed order is set forth in Paragraph XVI. In addition to supplying a copy of the proposed agreement at least 30 days in advance of its consummation, BMS is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the proposed order requires BMS to identify, among other things, all others known by BMS to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving BMS. In addition, BMS must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also provides a Hart-Scott-Rodino-type ''second request'' process in connection with the notice required by Paragraph XII.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The proposed order would expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–6078 Filed 3–12–03; 8:45 am]

BILLING CODE 6750–01–P

[21] See Abbott Labs., FTC Dkt. No. C–3945 (May 22, 2000); Geneva Pharms, FTC Dkt. No. C–3946 (May 22, 2000); Hoechst Marion Roussel, *et al.*, FTC Dkt. No. D.9293 (May 8, 2001).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03F–0088]

Ion Beam Applications; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ion Beam Applications has filed a petition proposing that the food additive regulations be amended by increasing

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