notice is given that a food additive petition (FAP 7A4769) has been filed by Dean Foods Co., c/o Hogan and Hartson LLP, 555 13th St., NW., Washington, DC 20004–1109. The petition proposes to amend the food additive regulations in part 172 *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172) to provide for the safe use of vitamin D_2 as a nutrient supplement in soy-based food products.

The agency has determined under 21 CFR 25.32(k) 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: September 26, 2007.

Laura M. Tarantino,

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

[FR Doc. E7–19576 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0356]

Behind the Counter Availability of Certain Drugs; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to obtain comments regarding behind-the-counter (BTC) availability of drugs. Currently, drugs are available as prescription and non-prescription. Generally, non-prescription products are available in an ''over-the-counter'' (OTC) manner. The FDA is interested in obtaining public comment as it explores the public health benefit of certain drugs being available without a prescription but only after intervention by a pharmacist. The purpose of the meeting is to solicit information and views from interested persons on specific issues associated with BTC availability, including the impact on patient access to safe and effective drug products.

Dates and Times: The public meeting will be held on November 14, 2007, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

ADDRESSES: Submit written registration and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*.

Submit electronic comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*. Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 30 days after the meeting.

For Registration to Attend and/or Participate in the Meeting: Seating at the meeting is limited. People interested in attending should submit written or electronic registration to the Division of Docket Management (see **ADDRESSES**) by close of business on November 5, 2007. Registration is free and will be on a first-come, first-serve basis. Written or electronic comments will be accepted until November 28, 2007.

If you wish to make an oral presentation at the meeting, you must state your intention on your registration submission (see **ADDRESSES**). To speak, submit your name, title, business affiliation, address, telephone number, fax number, and e-mail address. FDA has included questions for comment in this notice. You should also identify by number each question you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations due to a disability, please inform Erik Mettler (see *For Information on the Meeting Contact*).

For Information on the Meeting Contact: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *Erik.Mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to ensuring the safety and efficacy of all drug products it regulates. FDA is exploring the public health benefit of certain drugs being available BTC that were previously prescription medications. BTC could be comprised of certain medications available behind the counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing.

Some groups have asserted that pharmacist interaction with the consumer could ensure safe and effective use of a drug product that otherwise might require a prescription. Because pharmacists have the training and knowledge to provide certain interventions, they may be able to ensure that patients meet the conditions for use and educate patients on appropriate use of the drug product. These groups have suggested, moreover, that the availability of certain drugs BTC could increase patient access to medications that may be underutilized, particularly by patients without health insurance because these medications otherwise would be available only with a prescription.

Variations of a BTC status are already in effect in other countries, including Australia, Canada, France, New Zealand, United Kingdom (UK), Denmark, Germany, Italy, Netherlands, Sweden, and Switzerland. In the UK, there is a ''pharmacist-only'' class of drugs, while the other countries have more than three classes. In general, foreign countries have used the following criteria for switching a drug from prescription to intermediate class: (1) Indications suitable for self-medication, including self-diagnosis, with the intervention of a pharmacist and (2) the medicine has a low potential for side effects or overdose, and intervention by a pharmacist could minimize these risks. Other considerations include: Abuse potential, patient choice and accessibility, and public health issues. With the pharmacy-only classification, typically the pharmacist is required to ensure the patient meets certain criteria prior to dispensing, as well as to provide education on proper use and monitoring.

Accordingly, FDA is interested in exploring the public health implications of BTC dispensing of certain drug products, including (among other things) the implications for patient access and utilization, including drug prices, the continued safety and effectiveness of drugs, and patient compliance with drug therapy.

II. Scope of Meeting

FDA is interested in obtaining public comment on BTC availability of certain drugs, the appropriate regulatory

framework for such drugs, and criteria for BTC availability.

Specifically, we are seeking input on the following issues related to BTC:

General

1. Should there be BTC availability of certain drug products? If so why? If not why?
2. What might the impact of BTC be on patient access?
3. What might the impact of BTC be on patient compliance with drug therapy?
4. What should the criteria or standards be for a drug to be treated as BTC?
5. Please comment on the following criteria for what roles a pharmacist or other health professional might play, which are included below for discussion purposes. For example, a pharmacist or other practitioner licensed by law to dispense prescription drugs prior to sale might:

(A) Review or conduct an initial screening for clinical laboratory test results, contraindications, or drug interactions;

(B) Counsel the patient on safe use;

(C) Monitor for continued safe or effective use.

6. Should BTC availability be used as a temporary or transitional status for drugs that move from prescription status to OTC versus a permanent status?
7. Should there be criteria or standards for a drug to transition out of BTC status to OTC status? If so, what should these criteria or standards be?
8. If safety concerns arise, should there be criteria or standards for a drug to transition out of BTC status to prescription status? Or from OTC status to BTC status? If so what should these criteria or standards be for each scenario?
9. What effect would BTC availability have on patient access to medications in this category?
10. How could we evaluate whether BTC improves patient access to medications?
11. Would BTC availability be cost-effective to patients? Please explain.
12. What effect would BTC availability have on patient safety?
13. What measures would be necessary to ensure patient safety?
14. In general, what are the benefits and costs to the healthcare system as a whole related to BTC availability?

Logistics

1. Discuss logistical challenges for pharmacy storage and dispensing of BTC drugs. How might these challenges be addressed?
2. What dispensing procedures should be associated with BTC medications?
3. What types of records should be kept in association with BTC dispensing? If such records were to include patient laboratory values, how would the pharmacist gain access to this information as well as other information in the patient's medical records?
4. How would patient privacy be protected in a retail pharmacy setting? Please discuss any privacy concerns that would need to be addressed.
5. Should reimbursement be available to pharmacists for providing services associated with BTC dispensing? What type? What type of billing procedures could be utilized and how would third party companies facilitate such reimbursements?
6. Who would oversee a BTC program? What impact would it have on States and what might be the role for the State boards of pharmacy?
7. Would special training be needed for pharmacists to participate in dispensing BTC medications? If any, what type of training would this entail?
8. Would special training be needed for other pharmacy staff to aid in managing the work flow (storage, record keeping, distribution) and additional BTC responsibilities of the pharmacist(s) and the pharmacy? If so, what type of training or measures should be put in place?
9. Could qualified healthcare professionals/providers other than pharmacists be responsible for dispensing of BTC drugs? If so, what types of healthcare professionals/providers? And in what type of settings could this situation be accommodated?
10. What impact would BTC availability of drugs have on the practice of pharmacy?
11. What impact would BTC availability of drugs have on the practice of medicine?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the docket for the meeting will open 14 days prior to the meeting and remain open for 30 days following the meeting. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by the number and subject to which they refer in the previous text in this document. Please 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. Transcripts of the meeting also will be available for review at the Division of Dockets Management.

Dated: September 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19329 Filed 10–3–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. [2001D–0193 (formerly 01D–0193)]

Guidance for Industry and Food and Drug Administration Staff; Biological Indicator Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions.'' The agency is issuing this guidance document to provide information that will help manufacturers prepare premarket notification submissions for these devices. The document provides guidance regarding performance characteristics for biological indicator devices, which are intended to monitor the effectiveness of sterilizers used in healthcare facilities.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151 or 1–800–638–2041. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug