DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces fees for vessel sanitation inspections for fiscal year 2008 (October 1, 2007, through September 30, 2008).

DATES: *Effective Date:* October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Jaret Ames, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F–23, Atlanta, Georgia 30341–3724, telephone (770) 488–3139, E-mail: *Dforney@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Purpose and Background

The fee schedule for sanitation inspections of passenger cruise ships inspected under the Vessel Sanitation Program (VSP) was first published in the **Federal Register** on November 24, 1987 (52 FR 45019), and CDC began collecting fees on March 1, 1988. Since then, CDC has published the fee schedule annually. This notice announces fees effective October 1, 2007.

The formula used to determine the fees is as follows:

$$\frac{\text{Total cost of VSP}}{\text{Weighted number of annual inspections.}}$$

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060), and revised twice and published in the **Federal Register** on November 28, 1989 (54 FR 48942) and November 21, 2005 (70 FR 70078). The revised size/cost factor is presented in Appendix A.

Fee

The fee schedule (Appendix A) will be effective October 1, 2007, through September 30, 2008. If travel expenses continue to increase, the fees may need adjustment before September 30, 2008, because travel constitutes a sizable portion of VSP's costs. If an adjustment is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of CDC's VSP.

Dated: September 26, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention (CDC).

APPENDIX A

Vessel Size	GRT [1]	Approximate cost ($US) per GRT
SIZE/COST FACTOR		
Extra Small	< 3,001	0.25
Small	3,001–15,000	0.50
Medium	15,001–30,000	1.00
Large	30,001–60,000	1.50
Extra Large	60,001–120,000	2.00
Mega *	> 120,001	3.00
Vessel Size	GRT [1]	Fee ($US)
FEE SCHEDULE		
Extra Small	< 3,000	1,300
Small	3,001–15,000	2,600
Medium	15,001–30,000	5,200
Large	30,001–60,000	7,800
Extra Large	60,001–120,000	10,400
Mega *	>120,001	15,600

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.
* New Vessel Size Category.

Inspections and reinspections involve the same procedure, require the same amount of time, and are therefore charged at the same rate.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007F–0355]

Dean Foods Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dean Foods Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of vitamin D_2 as a nutrient supplement in soy-based food products.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1071.

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 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]

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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