informed FDA in June 1993 that its entire product line had been recalled following a change in management, and the agency has found no information that would lead it to conclude otherwise. Finally, FDA has also independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined above, Lannett Co.'s dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list dextroamphetamine sulfate tablets, 15 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to dextroamphetamine sulfate tablets, 15 mg, may be approved by the agency.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26473 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 14, 2002, from 8:30 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologics license application 125061/0, peginterferon alfa–2a copackaged with ribavirin, new drug application 21–511, Hoffmann-La Roche, Inc., proposed as combination therapy for the treatment of chronic hepatitis C.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner (see *Contact Person*) at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26615 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Security and Recalls; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) in cooperation with the Ohio State University, Department of Food Science and Technology is announcing a workshop for the food industry on food security and recalls. Topics for discussion include: Impact of U.S. bioterrorism legislation on the food industry, FDA and U.S. Department of Agriculture food safety and security guidance and procedures, product tampering investigations, tamper evident packaging in the food industry, preparing for and conducting a food recall, and opportunities to improve food security. This 1-day workshop is intended to target food manufacturers, repackers, and importers; and will include both industry and FDA perspectives on the prevention and handling of food security problems.

Date and Time: The public workshop will be held on Tuesday, November 19, 2002, from 8 a.m. to 4:15 p.m.

Location: The public workshop will be held at the University Plaza Hotel, 3110 Olentangy River Rd., Columbus, OH.

Contact: Marie Falcone, Industry and Small Business Representative, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–597–2120, ext. 4003, FAX 215–597–5798, e-mail: mfalcone@ora.fda.gov.

For registration information contact: Julie Townsend, 110 Parker Food Science and Technology Building, Ohio State University, 2015 Fyffe Rd., Columbus, OH 43210, e-mail: townsend.57@osu.edu, telephone 614–292–6281, FAX 614–292–2859. Send registration information (including name, title, firm name, address, telephone, and fax number) and the $90.00 registration fee made payable to Ohio State University to the Registrar Julie Townsend (address above). Electronic registration for this workshop is available at http://fst.osu.edu/recall.htm. The Registrar will also accept payment by Visa or Mastercard. Attendees are responsible for their own accommodations.

To make reservations at the University Plaza Hotel at the FDA Food

Security and Recalls Workshop rate of $75.00 (single) or $90.00 (double), contact the hotel at 877–677–5292 or 614–267–7461 before October 28, 2002. The workshop registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The Food Security and Recalls Workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by preventing and countering terrorism related to the nation's food supply. FDA has made providing security guidance and information to the food industry a high priority.

The workshop will help to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393(b) and (f)) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop will also further the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities directed to small businesses.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26618 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 18 and 19, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 2002, the committee will discuss the role of brain imaging as an outcome measure in phase 3 trials of putative therapeutic drugs for Alzheimer's disease; the discussions will not focus on specific drugs or on specific applications to the agency. The agency is considering whether brain imaging modalities can be utilized as surrogate markers; that is, as primary outcomes in definitive clinical trials to measure drug effect in lieu of clinical outcomes. The committee will specifically discuss the following issues in reference to each imaging modality:

1. How is the surrogate imaging modality best validated?

2. If one uses an imaging modality to support a disease-modifying effect claim, how does one establish that such an effect occurs?

3. Has any surrogate imaging modality been validated at the present time?

4. Even if no surrogate imaging modality has currently been validated, is it appropriate to use one or more such modalities as primary or ancillary outcome measures of efficacy in phase 3 clinical trials?

On November 19, 2002, the committee will consider a supplemental new drug application (NDA) 20–306 for F–18 fluorodeoxyglucose (FDG) positron emission tomography (PET) imaging proposed to diagnose and/or identify progression of Alzheimer's disease and other forms of dementia. This application is based on published multi-center controlled clinical trials, additional information provided by some of the literature authors, and other supportive literature. Considerations will include the relevance of current practice, knowledge of Alzheimer's disease process, and clinical trial design to establish clinical usefulness of F–18 FDG PET in Alzheimer's disease. (Downstate Medical Center, Peoria, IL, is the sponsor of the new drug application. The Academy of Molecular Imaging provided the literature references and the literature summary that formed the basis of the supplemental NDA.)

The background material will become available no later than the day before the meeting and will be posted under the Peripheral and Central Nervous Systems Drugs Advisory Committee docket site at: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2002 and scroll down to the Peripheral and Central Nervous Systems Drugs Advisory Committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2002. Oral presentations from the public will be scheduled between approximately 11 a.m. and noon each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26613 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S