

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for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn from sale for reasons of safety or effectiveness.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FDA determines that, for the reasons outlined above, Lannett Co.'s dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness.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.*

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## 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.*

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## 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