using this survey questionnaire will aid FDA in assessing risks that may be associated with vaccine product usage that are not foreseen or apparent during the premarket notification and review process, so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

In the **Federal Register** of June 27, 2002 (67 FR 43323) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
''A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1.''	225	1	225	0.5	112.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA projects that there will be up to 75 case subjects recruited into this study with 3 control subjects recruited for each case subject, with a total maximum of 225 survey questionnaire respondents. FDA also projects a response time no greater than 0.5 hours per response. This estimate is based on previous results experienced with the instrument during enhanced surveillance followup of adverse events reported to VAERS. Respondents will only be contacted once during conduct of this study for the purposes of collection of vital information using this survey questionnaire.

Dated: October 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26621 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01P–0252]

Determination That Dextroamphetamine Sulfate Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that dextroamphetamine sulfate 15-milligram (mg) tablets (formerly marketed by Lannett Co., Inc.) were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dextroamphetamine sulfate 15-mg tablets.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug which was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA's regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Dextroamphetamine sulfate tablets, 15 mg, are the subject of approved ANDA 85–652 held by Lannett Co., Inc. Dextroamphetamine sulfate tablets are indicated for narcolepsy and for attention deficit disorder with hyperactivity. Lannett Co., Inc.'s, dextroamphetamine sulfate 15-mg tablets are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

On May 17, 2001, Mallinckrodt, Inc., submitted a citizen petition (Docket No. 01P–0252/CP1) to FDA under 21 CFR 10.20 and 10.30. The petition, as amended July 26, 2001, requested that the agency determine that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from the market for reasons of safety or effectiveness.

The agency has determined that dextroamphetamine sulfate tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. There are several grounds for FDA's finding. First, there are drug products containing 15-mg dextroamphetamine sulfate being marketed today. Although these drug products are extended release products rather than immediate release products, FDA has concluded that this difference does not affect the product's safety. Second, the petitioner identified no data or other information suggesting that dextroamphetamine sulfate tablets, 15 mg, were withdrawn from sale as a result of safety or effectiveness concerns. Third, Lannett Company, Inc.,

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