TABLE 5.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]—Continued

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| Biologics | | | | | 6,714,066 |
| Total | | | | | 36,040,829 |

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

Dated: October 11, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–26617 Filed 10–17–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0259]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study; A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by November 18, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Telephone Questionnaire Administration to Control Subjects Recruited Into FDA Lyme Vaccine Safety Study entitled ''A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1''**

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct post-market surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system (VAERS) using form VAERS–1. Health care providers and manufacturers are required by law (42 U.S.C. 300aa–25) to report adverse events following vaccination listed in the vaccine injury table. Reports for reactions to other vaccines are voluntary and are received from vaccine recipients, their health care providers, and other reporters. FDA is seeking OMB clearance to collect vital information through the use of the proposed survey questionnaire for control subjects participating in this vaccine safety study. The intended respondents are control subjects previously recruited to participate in this study, and they are matched with case subjects reported to VAERS who developed arthritis following Lyme vaccine administration. Informed consent for administration of this questionnaire will have been received before the interview, and the interview is to be conducted at a time specified by the control subject at the time of initial recruitment into this study. Case and control subjects should have similar age, gender, and ethnic backgrounds. Specific genetic and immune factors will be compared between case and control subjects. This is a common, accepted type of epidemiological study called a case-control study. Information collected includes medical and vaccination history, family history, and possible exposures, such as in the workplace, that may play a part in the development of arthritis in some patients. FDA will use the information gathered from the use of this survey questionnaire to ensure appropriate matching of cases and controls in the study and to assess possible factors which may factor in the development of this adverse event. This study was approved by the FDA Research Involving Human Subjects Committee on February 15, 2002 (RIHSC 01–028B). This survey questionnaire is an abbreviated version of one used during enhanced surveillance followup of adverse events following Lyme vaccine administration reported to VAERS. The use of the vital information gathered

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.,