Place: Agency for Healthcare Research and Quality, 2101 East Jefferson Street, 4th Floor, ORREP, 4W5, Division of Scientific Review, Rockville, Maryland 20852.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594–1846.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: February 19, 2003.

Carolyn M. Clancy,

Director.

[FR Doc. 03–4531 Filed 2–25–03; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0038]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet; Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning Form FDA 3601 entitled ''Medical Device User Fee Cover Sheet,'' which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

DATES: Submit written or electronic comments on the collection of information by April 28, 2003.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments concerning the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Medical Device User Fee Cover Sheet; Form FDA 3601

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

Respondents to this collection of information are device manufacturers. Based on FDA's database system, there are an estimated 5,000 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2002. CDRH estimates 5,000 annual responses that include the following: 50 premarket approval applications, 4,400 premarket notifications, 30 modular premarket applications, 1 product development protocol, 1 premarket report, 20 panel track supplements, 150 real-time supplements, and 348 180-day supplements. CBER estimates 50 annual responses that include the following: 2 premarket approval applications, 3 biologics license applications, 30 premarket notifications, 10 modular premarket applications, and 5 180-day supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3601	5,000	1	5,000	.30	1,500

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

Dated: February 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4493 Filed 2–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1219]

Delmont Laboratories, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 299

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for hearing on a proposal to revoke the biologics license (U.S. License No. 299) issued to Delmont Laboratories, Inc. (Delmont), for Polyvalent Bacterial Antigens with ''no U.S. Standard of Potency'' (Staphage Lysate). The proposed revocation is based on FDA's proposed reclassification of this product in Category II (unsafe, ineffective, or misbranded), based on the recommendations of the Vaccines and Related Biological Products Advisory Committee (VRBPAC).

DATES: Delmont Laboratories, Inc., may submit written or electronic requests for a hearing by March 28, 2003, and any data and information justifying a hearing by April 28, 2003. Other interested persons may submit written or electronic comments on the proposed revocation by April 28, 2003.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests or comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 15, 2000 (65 FR 31003), FDA issued a proposed order to reclassify certain Category IIIA (remaining on the market pending further studies in support of effectiveness) bacterial vaccines and related biological products into Category I (safe, effective, and not misbranded) or Category II (unsafe, ineffective, or misbranded). This action was taken under the reclassification review procedures in § 601.26 (21 CFR 601.26), and was based on the findings and recommendations of the VRBPAC and the Panel on Review of Allergenic Extracts (the Allergenics Panel). The proposed order also announced our intent to revoke the biologics licenses for those bacterial vaccines and related products proposed for reclassification in Category II.

Based on VRBPAC's recommendations, FDA proposed that bacterial vaccines and toxoids with standards of potency be classified into two separate categories based upon their use as either a primary immunogen or as a booster. FDA further proposed that bacterial vaccines and related biological products with ''no U.S. standards of potency'' be classified into Category II for their labeled indications based on either the VRBPAC's or the Allergenics Panel's recommendations. Five manufacturers of Category IIIA products were subject to the proposed order, as listed in the following table:

TABLE 1—CATEGORY IIIA PRODUCTS PROPOSED BY FDA FOR RECLASSIFICATION INTO CATEGORY II AS A PRIMARY IMMUNOGEN OR FOR ALL LABELED INDICATIONS

Manufacturer/License Number	Product(s)	Proposed Category II Indication
Aventis Pasteur, Inc., No. 1277	Tetanus Toxoid (fluid)	Primary Immunogen
BioPort Corporation, No. 1260	Diphtheria and Tetanus Toxoids Adsorbed	Primary Immunogen
Wyeth Laboratories, Inc., No. 3	Tetanus and Diphtheria Toxoids Adsorbed (Adult Use)	Primary Immunogen
Delmont Laboratories, Inc., No. 299	Polyvalent Bacterial Antigens with ''No U.S. Standard of Potency'' (Staphage Lysate)	All Labeled Indications
Hollister-Stier Laboratories LLC, No. 1272 (1)	Polyvalent Bacterial Vaccines with ''No U.S. Standard of Potency'' (Bacterial Vaccines Mixed Respiratory (MRV or MRVI, Bacterial Vaccines for Treatment, Special Mixtures)	All Labeled Indications

[1] As described in the proposed order, this product was reviewed by the Allergenics Panel. The remaining products in this table were reviewed by the VRBPAC.

FDA also proposed that the bacterial vaccines with U.S. standards of potency recommended for classification into Category II as a primary immunogen be placed into Category I for use as a booster immunogen. Manufacturers who intended to market their products for use as a booster immunogen needed to submit supplements for changes to the container and package labels and the package insert, to include the statement, ''For Booster Use Only''.

Three of the five manufacturers submitted requests to voluntarily revoke their licenses. Accordingly, FDA revoked the licenses for: (1) Polyvalent Bacterial Vaccines with ''no U.S. Standard of Potency'' (Bacterial Vaccines Mixed Respiratory), Hollister-Stier Laboratories, U.S. license No. 1272, effective August 3, 2000 (66 FR