

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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.

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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 BioPort Corporation, No. 1260 Wyeth Laboratories, Inc., No. 3 Delmont Laboratories, Inc., No. 299	Tetanus Toxoid (fluid) Diphtheria and Tetanus Toxoids Adsorbed Tetanus and Diphtheria Toxoids Adsorbed (Adult Use) Polyvalent Bacterial Antigens with “No U.S. Standard of Potency” (Staphage Lysate)	Primary Immunogen Primary Immunogen Primary Immunogen 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

¹As 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