

*B. Burden Estimate*

Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment. The procedures for requesting special protocol assessment that are set forth in the guidance have not been previously described by the agency, although the PDUFA goals and the requirements of section 505(b)(4)(B) of the act (21 U.S.C. 355 (b)(4)(B)) have been in effect since October and November 1998, respectively, as follows:

1. Notification for a Carcinogenicity Protocol

Based on data collected from the review divisions and offices within CDER and CBER, including the number of carcinogenicity protocols submitted for review in the first half of fiscal year (FY) 1999 and the number of INDs for new molecular entities that were received by the agency per year over the last 5 years, CDER and CBER anticipate that approximately 30 respondents will notify the agency of an intent to request special protocol assessment of a carcinogenicity protocol. The agency further estimates that the total annual responses, i.e., the total number of notifications that will be sent to CDER and CBER, will be 60, based on data collected from the offices within CDER and CBER. Therefore, the agency estimates that there will be approximately two responses per respondent. The hours per response, which is the estimated number of hours that a respondent would spend

preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours. While FDA has not finalized the separate guidance describing background information that should be submitted with notification of a carcinogenicity protocol for assessment, the agency anticipates that it will take respondents approximately 8 hours to gather and copy articles and study reports that are relevant to the carcinogenicity protocol. Therefore, the agency estimates that respondents will spend 480 hours per year notifying the agency of an intent to request special protocol assessment of a carcinogenicity protocol.

2. Requests for Special Protocol Assessment

Based on data collected from the review divisions and offices within CDER and CBER, including the number of requests for special protocol assessment in the first half of FY 1999, the number of INDs for new molecular entities that were received by the agency per year over the past 5 years, the number of sponsors who have submitted protocols for agency review in the past and in the first half of FY 1999, and the number of end-of-phase 2/prephase 3 meetings that occur between respondents and the agency per year, FDA anticipates that 70 respondents will request special protocol assessment per year. The total annual responses are the total number of requests for special protocol assessment that are submitted

to CDER and CBER in 1 year. Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that it will receive approximately 180 requests for special protocol assessment per year. Therefore, the agency estimates that there will be approximately 2.57 responses per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on estimates provided by the regulated industry and on the agency's experience in requesting similar information, FDA estimates approximately 15 hours on average would be needed per response.

Therefore, FDA estimates that 2,700 hours will be spent per year by respondents requesting special protocol assessment. Overall, FDA anticipates that respondents will spend 3,180 hours per year to participate in the programs described in the guidance.

In the **Federal Register** of February 9, 2000 (65 FR 6377), the agency requested comments on the proposed collections of information. Eight comments were received, however they were related to the Protocol Assessment and not to the collection of information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| Notification and Requests                  | Number of Respondents | Number of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours  |
|--|-----------------------|------------------------------------|------------------------|--------------------|--------------|
| Notification for Carcinogenicity Protocols | 30                    | 2.0                                | 60                     | 8                  | 480          |
| Requests for Special Protocol Assessment   | 70                    | 2.57                               | 180                    | 15                 | 2,700        |
| <b>Total</b>                               |                       |                                    |                        |                    | <b>3,180</b> |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 18, 2001.  
**Margaret M. Dotzel,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 00N-1219]**

**Biological Products; Bacterial Vaccines and Related Biological Products; Revocation of Biologics Licenses**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of certain biologics licenses. This action was taken at the voluntary request of the licensees in response to a proposed order for the Implementation of Efficacy Review for Bacterial Vaccines and Related Biological Products.

**DATES:** The revocation of the biologics license for the manufacture of

Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," manufactured by Hollister-Stier Laboratories, LLC, U.S. license 1272, became effective August 3, 2000. The revocation of the biologics license for the manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids Adsorbed, Diphtheria Toxoid Adsorbed, and Tetanus Toxoid Adsorbed, manufactured by BioPort Corp., U.S. license 1260, became effective November 20, 2000. Other products under these licenses are not affected by this revocation.

**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 a notice published in the *Federal Register* of May 15, 2000 (65 FR 31003), FDA issued a proposed order to accept the conclusions and recommendations of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the Panel on Review of Allergenic Extracts (the Allergenic Panel) concerning the safety, effectiveness, and labeling of certain bacterial vaccines and related biological products that were previously classified into Category IIIA (remaining on the market pending further studies in support of effectiveness). On the basis of the Allergenic Panel and the VRBPAC findings, FDA proposed to reclassify certain Category IIIA 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 specified in 21 CFR 601.26. The proposed order also announced the agency's intention to revoke the biologics licenses for those bacterial vaccines and related products classified as Category II (unsafe, ineffective, or misbranded).

Certain Category IIIA bacterial vaccines and toxoids with standards of potency listed in the proposed order were classified into two categories based upon their use as a primary immunogen or as a booster. Diphtheria and Tetanus Toxoids Adsorbed, and Tetanus Toxoid Adsorbed manufactured by BioPort Corp. were recommended by the VRBPAC for classification into Category II (unsafe, ineffective, or misbranded) for primary immunization and Category I (safe, effective, and not misbranded) for booster immunization.

Similarly, certain bacterial vaccines and related biological products listed in

the proposed order were recommended for classification into Category II for both diagnosis and immunotherapy by the Allergenic Panel. Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," manufactured by Hollister-Stier Laboratories, LLC, was recommended for classification into Category II for both diagnosis and immunotherapy by the Allergenic Panel.

FDA agreed with the recommendations of the VRBPAC and the Allergenic Panel to reclassify the above cited products into Category II for their respective indications, and in the proposed order provided notice of the agency's intent to revoke the licenses to manufacture these products. On June 19, 2000, Hollister-Stier Laboratories, LLC, submitted a letter to FDA voluntarily requesting revocation of its license to manufacture Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency." On August 9, 2000, BioPort Corp. submitted a letter to FDA voluntarily requesting revocation of its license to manufacture Diphtheria and Tetanus Toxoids Adsorbed, and Tetanus Toxoid Adsorbed. In its August 9, 2000, letter, BioPort Corp. also voluntarily requested revocation of its license to manufacture Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, and Diphtheria Toxoid Adsorbed, although these products were not included in the proposed order.

The proposed order announced that the agency would publish a notice of opportunity for a hearing on the revocation of the license of each product classified in Category II. BioPort Corp. and Hollister-Stier Laboratories waived their opportunity for a hearing when they voluntarily requested license revocation for their reclassified Category II products.

Accordingly, under the provisions of 21 CFR 601.5(a), section 351 of the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), FDA revoked the biologics license issued to Hollister-Stier Laboratories, LLC, U.S. license 1272, for the manufacture of Polyvalent Bacterial Vaccines with "no U.S. Standard of Potency," effective August 3, 2000; and FDA revoked the biologics license issued to BioPort Corp., U.S. license 1260, for the manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids Adsorbed, Diphtheria Toxoid Adsorbed, and Tetanus Toxoid Adsorbed effective November 20, 2000.

Dated: May 9, 2001.

**Kathryn C. Zoon,**

*Director, Center for Biologics Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96P-0484]

#### Blood Products Advisory Committee, Medical Devices Panel; Reclassification of Autopheresis-C® System From Class III to Class II

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

**ACTION:** Notice of panel recommendation.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the Blood Products Advisory Committee, Medical Devices Panel (the Panel) to reclassify the Autopheresis-C® System, intended for routine collection of blood and blood components, from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by Baxter Healthcare Corp. (Baxter). FDA is also issuing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the *Federal Register*.

**DATES:** Submit written comments by August 13, 2001.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background (Regulatory Authorities)**

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the