

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. 00D-0084]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry on Special Protocol Assessment

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 (PRA).

DATES: Submit written comments on the collection of information by June 28, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION:

I. Background

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

Guidance for Industry on Special Protocol Assessment

FDA is issuing a guidance on agency procedures to evaluate issues related to the adequacy of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency will interpret and apply provisions of the Food and Drug Administration Modernization Act of

1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products.

The guidance describes two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol, and (2) the submission of a request for special protocol assessment.

II. Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol. The agency is currently drafting a separate guidance describing the type of information that would be appropriate to submit before requesting carcinogenicity protocol assessment.

III. Request for Special Protocol Assessment

In the guidance, CDER and CBER ask that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the agency in triplicate with Form FDA 1571 attached. The agency also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been

approved by OMB until September 30, 2002, under the OMB control number 0910-0014. In the **Federal Register** of May 6, 1999 (64 FR 24402), FDA published a notice requesting comments on the burden estimates for the information collection requirements in part 312. The notice also requested an extension of OMB approval for this information collection.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable agency staff to prepare for the arrival of the protocol for assessment. The agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for stability protocol, product characterization and relevant manufacturing data.

A. Description of Respondents

A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the Federal Food, Drug, and Cosmetic Act (the act) or section 351 of the Public Health Service Act who requests special protocol assessment.

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 BURDEN¹

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
Total					3,180

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

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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