I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol'' November July 2000. The guidance document provides information to FDA reviewers regarding broader relative potency limits for CBER evaluation of standardized dust mite and grass allergen vaccines submitted to CBER for lot release. Issues addressed in the guidance document include, but are not limited to, the following: (1) Diagnostic equivalence, (2) theraputic equivalence, (3) safety equivalence, (4) lot-to-lot variation in allergen vaccine potency, and (5) current and broadened CBER release limits for standardized dust mite and grass allergen vaccines submitted to CBER for lot release. The guidance document announced in this notice finalizes the draft guidance entitled, ''Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol'' that was announced in the **Federal Register** on February 15, 2000 (65 FR 7557).

This guidance document represents the agency's current thinking with regard to the potency limits for standardized dust mite and grass allergen vaccines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: October 13, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29537 Filed 11–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–3010]

''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' dated November 2000. The guidance document provides information on developing stability protocols for standardized grass pollen extracts. The development of suitable stability studies is necessary to determine the shelf life of standardized grass pollen extracts to help ensure the safety, purity, and potency of these products. The guidance document announced in this notice finalizes the draft guidance entitled ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' that was announced in the **Federal Register** of August 25, 1997.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' dated November 2000 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, 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

FDA is announcing the availability of a document entitled ''Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' dated November 2000. The guidance document is intended to provide information to manufacturers regarding stability studies on grass pollen extracts. Such stability studies are used to determine the shelf life of the product. This guidance document does not, however, change lot release criteria for these products. Issues addressed in the guidance document include, but are not limited to: (1) Current lot release criteria, (2) lot release versus stability protocol, (3) modified stability protocol, (4) retesting, (5) dealing with test failure, and (6) extension of dating. The guidance document announced in this notice finalizes the draft guidance entitled ''Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts'' that was announced in the **Federal Register** of August 25, 1997 (62 FR 44975).

This guidance document represents the agency's current thinking with regard to the testing limits in stability protocols for standardized grass pollen extract. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two

copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: November 6, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29535 Filed 11–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Year 2000 Community Health Center and National Health Service Corps User/Visit Survey (OMB No. 0915–0185)—Reinstatement, With Change

The purpose of this study is to conduct a sample survey which has three components: (1) A pilot study, including an evaluation of both retrospective and prospective sampling methodologies; (2) a personal interview survey of Community Health Center (CHC) and National Health Service Corps (NHSC) site users; and (3) a record-based study of visits to CHCs and NHSC sites. CHCs and NHSC sites serve predominantly poor minority medically underserved populations. The proposed user and visit survey will collect in-depth information about CHC and NHSC site users, their health status, the reasons they seek care, their diagnoses, and the services utilized in a medical encounter.

The Year 2000 User/Visit Survey was developed using similar questionnaire methodology from the 1995 User/Visit Survey in conjunction with a contractor and will allow longitudinal comparisons for CHCs with the 1995 version of the survey data, including monitoring of process outcomes over time. The Year 2000 User/Visit Survey is the first year that NHSC non-grantee, freestanding sites will be surveyed.

The estimated response burden for the pilot test is as follows:

Form	Number of respondents	Responses per respondent	Total respondents	Hours per response	Total burden hours
Site Induction	10 (sites)	1	10	1	10
Site Sampling Methods: Retrospective & Prospective.	10 (sites)	1	10	1.5	15
User Survey Tracing Procedures	20 users at 10 sites	1	200	.5	100
User Survey	3 users at 10 sites	1	30	2.25	67.5
Visit Survey	10 (sites)	30	300	.5	150
Total	260		550		342.5

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 13, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–29539 Filed 11–17–00; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Substance Abuse Prevention and Treatment (SAPT) Block Grant Application Guidance and Instructions, FY 2002—2004 (OMB No. 0930–0080, Revision)—Sections 1921 through 1935 of the Public Health Service Act (U.S.C. 300x–21 to 300x–35)