Notice of this meeting is given under the Federal Advisory committee Act (5 U.S.C. app. 2).

Dated: July 18, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–14455 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0492] (formerly Docket No. 02D–0492)

Guidance for Industry on Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' This guidance provides a description and basis for a process by which to select a maximum recommended starting dose (MRSD) for a first-in-human clinical trial of a therapeutic in adult healthy volunteers.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lois M. Freed, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2647.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' This guidance provides a description and basis for a process by which to select an MRSD for a first-in-human clinical trial of a new molecular entity in adult healthy volunteers. In the **Federal Register** of January 16, 2003 (68 FR 2340), FDA published a notice making available a draft guidance entitled ''Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers.'' The notice gave interested persons an opportunity to submit comments. As a result of the comments, certain sections of this guidance were reworded to improve clarity. The guidance outlines a recommended standardized approach (including common conversion factors for calculating human equivalent doses) and vocabulary for selecting an MRSD based on animal data, and discusses factors to be considered in determining reasonable safety margins. This approach is applicable to a first-in-human trial of a new drug or biological therapeutic, regardless of intended clinical use. The guidance also discusses alternative approaches and provides some examples of circumstances under which alternative approaches for selection of an MRSD should be considered. Dose escalation is not addressed.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on estimating the maximum safe starting dose in initial clinical trials for therapeutics in adult healthy volunteers. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14456 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

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 (OMB), 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: The National Health Service Corps Uniform Data System (OMB No. 0915–0232): Revision

The National Health Service Corps (NHSC) of the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The NHSC needs to collect data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The following information will be collected from each site: services offered and delivery method; users by various characteristics; staffing and utilization; charges and

collections; receivables, income, and expenses; and managed care.

The estimated burden is as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Universal Report	1200	1	27	32,400

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

Dated: July 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–14484 Filed 7–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as amended 68 FR 787–93, January 7, 2003; as amended at 68 FR 8515–8517, February 21, 2003, as last amended 69 FR 56433–56445, September 21, 2004.)

This notice reflects several revisions to the organizational and functional statements of the Bureau of Primary Health Care. Specifically, this notice (1) Renames the Division of Health Center Development to the Division of Policy and Development; (2) Moves the policy function from the Office of the Director; (3) Establishes the Policy Branch in the Division of Policy and Development; and (4) Establishes a new description for the Division Director.

Section RC–00 Mission

The Bureau of Primary Health Care (BPHC) directs national health programs which improve the health of the Nation by assuring access to high quality comprehensive preventive and primary health care services and improving the health status of the Nation's underserved and vulnerable populations.

Section RC–10 Organization

The Bureau of Primary Health Care (BPHC) headed by the Associate Administrator for Primary Health Care reports directly to the Administrator, Health Resources and Services Administration. BPHC includes the following components:

(1) Office of the Associate Administrator (RC)

(2) Office of Minority and Special Populations (RCE)

(3) Division of Policy and Development (RCH)

(4) Division of Health Center Management (RCJ)

(5) Division of Clinical Quality (RCK)

(6) Division of State and Community Assistance (RCL)

(7) Division of National Hansen's Disease Program (RC7)

(8) Division of Immigration Health Services (RC9)

Remove the policy function from the Office of the Associate Administrator and place it in the Division of Policy and Development; and change the functional statement as follows: The Division of Policy and Development (RCH) serves as the organizational focus of the competitive grant process for BPHC; and leads in drafting policy and conducting analyses of performance across BPHC's programs. Specifically, the Division of Policy and Development executes the following activities: (1) Leads and monitors the development and expansion of health centers and health systems infrastructure; (2) provides pre-application assistance to communities and community-based organizations related to the development and expansion of health centers and health systems infrastructure; (3) consults and coordinates with other components within HRSA, other Federal agencies, consumer and constituency groups, and national and State organizations on issues affecting BPHC's programs; (4) formulates budget justifications for BPHC's programs and provides input into the analysis of BPHC budget execution; (5) leads and coordinates the analysis, development and drafting of policy impacting BPHC's programs; (6) performs environmental scanning on issues that affect BPHC's programs; (7) serves as the focal point for designing and implementing a plan for assessing and improving program performance; and (8) serves as the focal point for monitoring BPHC's activities in relation to HRSA's Strategic Plan.

Revise the functional statement for the Office of the Associate Administrator as follows: Provides overall leadership, direction, coordination, and strategic planning in support of Bureau programs. Specifically: (1) Has lead responsibility to bring primary health care services to the Nation's neediest communities; (2) serves as a central point of contact for Bureau communication and information; (3) establishes program policies, goals, and objectives and provides oversight as to their execution; (4) interprets program policies, guidelines, and priorities; (5) stimulates, coordinates and evaluates program development and progress; (6) maintains effective relationships with HRSA, other Department and Health and Human Services (HHS) organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with primary health and improving the health status of the Nation's underserved and vulnerable populations; and (7) plans, directs, coordinates and evaluates Bureau-wide administrative management activities; (8) assures BPHC's funding recommendations are consistent with authorizing legislation, program expectations and HHS and HRSA policies.

Section RC–30 Delegation of Authority

All delegations of authority which were in effect immediately prior to the effective date hereof have been continued in effect in them or their successors pending further re-delegation. I hereby ratify and affirm all actions taken by any HHS official which involves the exercise of these authorities prior to the effective date of this delegation.

This reorganization is effective upon the date of signature.