information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. The Marketing Practices and Communications Branch of FDA's Division of Drug Marketing, Advertising, and Communications is studying the effectiveness of various formats for the presentation of risk and benefit information for over-the-counter (OTC) and prescription drugs to male and female patients through patient labeling. To gain information about the value and utility of benefit and risk information presented in several formats, three studies will be undertaken. In each study subjects will examine materials varied by one or more risk formatting variables for one prescription and one OTC drug. Subjects will be recruited at large shopping malls. They will be brought to a private interview room where they will examine the materials, and a structured interview will be conducted. Equal numbers of subjects of each gender will be included in each study. In addition, there will be a control group for each study that receives ''no-risk'' information labels for the drugs. There will be 2,160 experimental subjects and 540 control subjects, for a total of 2,700 respondents.

ESTIMATED ANNUAL REPORTING BURDEN

No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
2,700	1	1	.5	1,350

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

Dated: April 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–10302 Filed 4–25–96; 8:45 am]

BILLING CODE 4610–01–M

[Docket No. 96D–0132]

Guidance Concerning Demonstration of Comparability of Human Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products.'' Manufacturing process, equipment, and/or facilities changes have the potential to alter a product and affect its safety, identity, purity, and potency. Therefore, manufacturers should carefully assess such changes and should evaluate the product resulting from these changes for comparability to the pre-existing product. This guidance document is intended to address the concept of comparability and delineates those analyses that manufacturers should perform and which FDA will evaluate to allow more rapid implementation of manufacturing changes for these types of products.

DATES: Written comments may be submitted at any time, however, to ensure comments are considered for the next revision, they should be submitted by July 25, 1996.

ADDRESSES: *CBER Information*: Submit written requests for single copies of the document entitled ''FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products'' to the Division of Congressional and Public Affairs (HFM–44), 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 that office in processing your requests. The document may also be obtained by FAX by calling the CBER Voice Information System at 1–800–835–4709. Persons with access to the INTERNET may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators (URL's):http://www.fda.gov/cber/cberftp.htmlftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requesters should connect to the FDA FTP Server, FTP.FDA.GOV (192.73.61.21). The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail''. A message should be sent to: ''comptest@a1.cber.fda.gov''.

CDER Information: For additional copies of this guidance, contact the Division of Communications Management (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fisher's Lane, Rockville, MD 20857, 301–594–1012. Send one self-addressed adhesive label to assist that office in processing your requests. An electronic version of this guidance is also available via Internet using FTP, Gopher or the World Wide Web (WWW). For FTP, connect to the CDER anonymous FTP server at cdvs2.cder.fda.gov and change to the ''guidance'' directory. For Gopher, connect to the CDER Gopher server at gopher.cder.fda.gov and select the ''Industry Guidance'' menu option. For WWW, connect to the FDA Home Page at http://www.fda.gov./fdahomepage.htlm.

Submit written comments on the document to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Corporations should submit two copies of any comments and individuals may submit one copy. Requests and 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.

FOR FURTHER INFORMATION CONTACT: Annette Ragosta, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA acknowledges that changes in product manufacture may occur during product development and subsequent to product approval. Manufacturers frequently upgrade and refine a product's production process as technology advances and as they gain experience with the product. Historically, because of the limited ability to characterize the identity and structure of the clinically active component(s) and measure its activity, a biological product was often defined by its manufacturing process, and manufacturers of biological products sought to minimize changes to the manufacturing process to avoid performing additional clinical studies to verify the safety, purity, and potency of the finished product. Due to advances in biologics research and manufacturing, including the ability to make well-characterized biotechnology-derived products, a manufacturer may change a manufacturing process without FDA requiring additional clinical studies if test data demonstrate that the product is comparable to the product manufactured before the change. Therefore, FDA is publishing this guidance document to further clarify situations in which sponsors may make manufacturing changes and perform comparability testing to assure that the approved product is pure, potent, and safe.

Manufacturers should perform comparability testing to demonstrate that identity, purity, potency, and safety of the product have not been affected by changes in the manufacturing process, equipment, or facilities. This guidance document discusses principles and categories of tests which may be performed to demonstrate product comparability, but does not discuss specific manufacturing changes. Comparability testing programs may include a combination of analytical testing, bioassays, preclinical animal studies, and clinical studies. Since each product may present unique concerns, the type of change, the relevance of validated analytical and biological assays used, the stage of product development, and the clinical program should be considered by manufacturers when designing a comparability program. FDA will take all of these into consideration when reviewing the comparability data that are submitted. Sponsors are encouraged to discuss proposed testing programs with FDA before implementing them, especially in those cases where they expect differences to result from the manufacturing changes. This document does not describe how changes are to be reported or which changes require prior approval. Manufacturers should consult current regulations and guidance documents regarding reporting and approval submissions.

As with other guidance documents, FDA does not intend this document to be all inclusive. The document is intended to provide information and does not set forth requirements. Manufacturers may follow the document or may choose to use alternative procedures that are not provided in this document. If a manufacturer chooses to use alternative procedures, that manufacturer may wish to discuss the matter further with FDA to prevent expenditure of resources to generate data on activities that FDA may later determine to be unacceptable.

Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, it does represent the agency's current thinking on the demonstration of comparability of human biological products, including therapeutic biotechnology-derived products.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. FDA will review the comments received and if appropriate consider preparing a revised guidance document based upon that review. However, CBER notes that it has made comparability assessments when approving /products in the past and will continue to do so during the comment period. FDA will announce the availability of this revised guidance document in the Federal Register if FDA revises its comparability policy as a result of public comment.

Dated: April 22, 1996

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–10426 Filed 4–25–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Maternal and Child Health Services; Federal Set-Aside Program; Continuing Education and Development Cooperative Agreements

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS) Continuing Education and Development (CED) cooperative agreements to support national education, information, and public policy projects in maternal and child health. Awards will be made under the program authority of section 502(a)(2)(A) of the Social Security Act, the training provision of the MCH Federal Set-Aside Program. SPRANS training projects may be awarded only to public or nonprofit private institutions of higher learning. Within the HRSA, MCH CED cooperative agreements are administered by the Maternal and Child Health Bureau (MCHB). Awards under this announcement are made for grant periods of up to 5 years in duration.

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the SPRANS program, the amount of available funding for this specific grant program cannot be estimated.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the