is Greensboro, North Carolina. The populations consist primarily of African-Americans. Health care providers will be identified and solicited from practicing physicians in Raleigh and Greensboro.

The survey will be conducted in four phases. Phase I will randomly identify and solicit participation from household members with and without diabetes from the control and intervention communities. In Phase II, participants with and without diabetes will be randomly selected and administered the survey questionnaire upon granting informed consent. During Phase III, persons with diabetes will undergo a brief physical exam that will consist of physical measures for height, weight, blood pressure, and body mass index. In addition, collection of a venous blood sample and urine sample will be performed. In Phase IV, interviewers will administer a questionnaire to primary care physicians about their knowledge, attitude and practice patterns for caring for persons with diabetes. This study will undergo Institutional Review Board reviews and comply with human subject assurances in accordance with federal regulations. The total cost to respondents is estimated at $41,160.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Households	8,000	1	0.3333	2,666
Persons without diabetes	1,600	1	0.5	800
Persons with diabetes	600	1	0.5	300
Primary Care Physicians	140	1	0.5	70
Total				3,836

6. National Disease Surveillance Program I—(0920–0009)—Extension—Formal surveillance of 21 separate reportable diseases has been ongoing to meet the public demand and scientific interest for accurate, consistent epidemiologic data. The diseases include: HIV/AIDS, bacterial meningitis, dengue, idiopathic CD4+ T-lymphocytopenia, kawasaki syndrome, legionellosis, Hansen's Disease, lyme disease, malaria, pertussis, plague, poliomyelitis, psittacosis, Reye Syndrome, Rocky Mountain Spotted Fever, Tetanus, Toxic Shock Syndrome, toxocariasis, trichinosis, typhoid fever, and viral hepatitis. Case report forms enable CDC to collect demographic, clinical, and laboratory characteristics of cases of these diseases. This information is used to direct epidemiologic investigations, to identify and monitor trends in reemerging infectious diseases or emerging modes of transmission, to search for possible causes or sources of the diseases, and to develop guidelines for prevention and or treatment. It is also used to recommend target areas in most need of vaccinations for certain diseases and to determine development of drug resistance.

Because of the distinct nature of each of the diseases, the number of cases reported annually is different for each. The total cost to respondents is estimated at $818,184.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden response (in hrs.)	Total burden (in hrs.)
Health Care Workers	125,214	1	0.5	34,091
Total				34,091

Dated: April 22, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–10356 Filed 4–25–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0010]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of male and female consumers regarding various formats for presenting risk and benefit information in drug labeling.

DATES: Submit written comments by June 25, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide 60-day notice in the Federal Register concerning each proposed collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of

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