Statistics.'' The report outlines themes that have emerged from national consultations involving health statistics users, public health providers, advocacy groups and health care providers at local, state, and Federal levels. Speakers invited by the 21st Century Workgroup will be asked to discuss specific local and state health statistics needs, specific means for generating private and public cooperation in defining health statistics needs and generating health statistics collaborations. Invited speakers will also be asked to provide specific comments and suggestions on the interim report, particularly as it relates to local and state health statistics needs and private and public cooperation.

The October hearing is the second of a series of joint public hearings to be conducted in several regions of the country through the fall of 2000 to solicit testimony on the reports. Information from the hearings will be incorporated in the final reports expected to be completed in early 2001.

Persons who would like to make a brief oral comment (3–5 minutes) during the October hearing will be placed on the agenda as time permits. To be included on the agenda, please submit testimony by October 13, 2000, to Patrice Upchurch at (301) 458–4540, by e-mail at pupchurch@cdc.gov, or postal address at NCHS, Presidential Building, Room 1100, 6525 Belcrest Road, Hyattsville, Maryland 20782. Persons wishing to submit written testimony only (no more than 2–3 typewritten pages) should also adhere to the due date of October 13, 2000. Testimony will also be accepted on-site as time permits. Please consult Ms. Upchurch for further information about these arrangements. Additional information about the meeting will be provided on the NCVHS homepage at: http//www.ncvhs.hhs.gov/ shortly before the meeting date.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: http://www.ncvhs.hhs.gov/.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–23913 Filed 9–15–00; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–00–50]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Office at (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is 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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Questionnaire Design Research Laboratory (QDRL) 2001–2003, (OMB No. 0920–0222)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The QDRL conducts pretesting activities related to the development of NCHS and other Federal survey questionnaires, such as the National Health Interview Survey (NHIS). These activities mainly involve use of the cognitive interview, in which volunteer respondents (''laboratory subjects'') are administered draft survey questions, and are asked to react to those questions. The cognitive interviewer notes sources of error in these questions, based on problems that subjects have in comprehending the questions and in attempting to recall the information requested. After several cycles of testing of small numbers of respondents (generally 10–12), and development of the questions between testing ''rounds,'' the questionnaires are improved to the point to which they are ready for field testing and household administration. QDRL staff are also engaged in the conduct of general questionnaire design research, in which survey questions are administered to laboratory subjects using different phrases, or under different administration modes (*e.g.,* face-to-face versus telephone), in order to determine the optimal means for presenting the questions. These investigative pretesting activities are now routinely used by NCHS and by other survey organizations for testing and development purposes, and result in high data quality at a minimal cost, especially in terms of respondent burden. We also support field testing on occasion to assure adequate pretesting of health survey instruments. There are no net cost to respondents because they receive remuneration.

Respondents	Number of respondents	Number of responses per respondent	Avg. burden response (in hours)	Response burden (hour)
2001 test volunteers	500	1	1.2	600
2002 test volunteers	500	1	1.2	600
2003 test volunteers	500	1	1.2	600
Total				600

Dated: September 12, 2000.

Nancy Cheal,

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

[FR Doc. 00–23859 Filed 9–15–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1489]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation

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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements associated with sterility requirements for aqueous-based drug products for oral inhalation.

DATES: Submit written or electronic comments on the collection of information by November 17, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at http://www.accessdata.fda.gov/scripts/oc/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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 through the use of automated collection techniques, when appropriate, and other forms of information technology.

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (formerly known and approved under Sterility Requirements for Inhalation Solution Products) (OMB Control No. 0910–0353)

Sections 314.70(b) and 314.97 (21 CFR 314.70(b) and 314.97) require that all aqueous-based drug products for oral inhalation, including those currently approved, be manufactured sterile. Respondents will be required to submit a supplemental application under § 314.70(b) or § 314.97, describing their new manufacturing process for achieving sterility of their aqueous-based drug products for oral inhalation. FDA needs this information to determine compliance with this new regulation and will use information collected to make decisions on approval of supplemental applications.

Based on new information collected by its contractor, ERG, FDA has revised its estimate of the number of respondents in the original proposal for reporting and recordkeeping burden. Because the respondents have changed, the estimate of the total hours have changed. In the proposed rule it was estimated that there were 5 manufacturers, while the final rule estimates there are 8 manufacturers with 11 nonsterile products based on new data collected by ERG. However, four of the manufacturers are projected to cease manufacturing, leaving four companies manufacturing seven products. These companies are projected to cease manufacturing because they may lack the in-house technical capability to convert their operations or might find the prospective investments in sterile production technologies to be unattractive. Because each nonsterile product will require an annual report (21 CFR 314.81(b)(2)(iv)), the number of annual responses for nonsterile products has increased to seven. Based on a review of FDA's past experience with applicants submitting supplemental applications under § 314.97, we estimate 160 hours to prepare a supplemental application. Therefore, due to the increased estimate of respondents, the total hours for the annual reporting burden for manufacturers of nonsterile products has increased from 800 hours in the proposed rule to 1,120 hours in the final rule. The agency's review of the estimated reporting burden for manufacturers of sterile products in the proposed rule and its experience with the annual reporting burden for manufacturers of sterile products supported the estimate provided in the proposed rule. Therefore, the estimated reporting burden for manufacturers of sterile products is the same as in the proposed rule.

Respondents to this information collection are businesses engaged in the manufacture of aqueous-based drug products for oral inhalation.

FDA estimates the burden of this collection of information as follows: