Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' that appears elsewhere in this issue of the **Federal Register**.

DATES: Submit comments at any time.

ADDRESSES: Submit written comments on GFI #78 to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FDA will also accept electronic comments. Persons who wish to submit electronic comments should go to the FDA home page at www.fda.gov and select ''Dockets'' and follow the instructions.

Submit written requests for single copies of the document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See section **III. Electronic Access** of this document for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Thompson, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA announced the availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). This draft guidance announced that FDA believed that it is necessary to evaluate the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. The publication of the draft of GFI #78 was the first step in the agency's consideration of the issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft of GFI #78 laid out the agency's rationale for its current thinking about its authority under section 512 of the act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals.

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (Framework Document). The Framework Document was the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health. The Framework Document is related to GFI #78 in that it sets out a conceptual risk-based framework for evaluating the microbial safety (related to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals.

After considering comments received by the public for both the draft of GFI #78 and the Framework Document, FDA determined that it was necessary to make some revisions to GFI #78. The revisions are intended to make GFI #78 more clearly reflect the agency's intentions regarding this issue. For example, the words ''evaluate'' and ''evaluation'' have been changed to ''consider'' and ''consideration,'' and other changes have been made to indicate that additional testing would not always be needed to determine the potential human health impact of the microbial effects associated with antimicrobial new animal drugs intended for use in food-producing animals.

GFI #78 represents the agency's current thinking on how under section 512 of the act it intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. It does not create or confer any right 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 statute, regulations, or both.

II. Comments

Interested persons may, at any time, submit written or electronic comments on GFI #78 to the Dockets Management Branch (address above). Two copies of written comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. GFI #78 and written and electronic 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 copies of ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) at http://www.fda.gov/cvm.

Dated: December 8, 1999.

Margaret M. Dotzel

Acting Associate Commissioner for Policy.

[FR Doc. 99–32324 Filed 12–14–99; 4:09 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

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.

Proposed Project: Social Support for Homeless Mothers: Implications for Best Practices and Program Design—New

The Health Care for the Homeless Clinicians' Network (HCHCN) of the National Health Care for the Homeless Council, Inc., through a cooperative agreement with the Bureau of Primary Health Care, Health Resources and Services Administration, proposes to conduct a study on the social support available to homeless mothers, most of whom are parenting children alone. The study will be of adult homeless women and will be conducted by convening focus groups and administering a questionnaire to focus group members. The study is designed to look at clients' life events, histories of violence, medical and physical illness, social support, children's needs, and services use. The results will help to define best practices as they relate to social support processes and enable HCH programs to offer the appropriate mix of supports necessary to help mothers transition into permanent housing. The participants will be recruited from ten sites of the national Health Care for the Homeless program.

The estimated response burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Patient	100	1	3	300
Total	100			300

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 2, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–32755 Filed 12–16–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request: American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) Final Evaluation: ''Tobacco Use Supplement to the 1998–2000 Current Population Survey''

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 14, 1999, pages 49814–49815 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION:

Title: American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) Final Evaluation: ''Tobacco Use Supplement to the 1998–2000 Current Population Survey.''

Type of Information Request: OMB No. 0925–0368, Exp. 12/31/99, REVISION.

Need and Use of Information Collection: The ''Tobacco Use'' supplement to the Current Population Survey conducted by the Bureau of the Census collected data in September 1998 and January and May 1999 from the civilian non-instititionalized population on tobacco use and smoking prevalence, smoking intervention dissemination of workplace smoking policies and cessation programs as well as medical and dental advice to stop smoking, and changes in smoking norms and attitudes. Due to an administrative error, in January and May 1999 data collection included a small set of incorrect questions which does not permit an accurate estimate of total tobacco use. The proposed information collection will ask the correct set of questions (comparable to the correctly fielded set in September 1998) for other tobacco usage (cigars, pipes, chewing tobacco and snuff), along with the standard cigarette smoking prevalence questions in order to estimate total tobacco usage. This survey will provide valuable information to Government agencies and to the general public necessary for tobacco control research. The data will be used by the National Cancer Institute to evaluate the effectiveness of the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST), a large scale 17 state demonstration project. The survey will allow state specific estimates to be made. Data will be collected in January 2000 and May 2000 from approximately 170,000 respondents.

Frequency of Response: One-time study.

Affected Public: Individuals or households.

Type of Respondents: Persons 15 yrs of age or older. The annual reporting burden is as follows.

Estimated Number of Respondents: 170,000.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: 0.0113; and

Estimated Total Annual Burden Hours Requested: 1921.

The annualized cost to respondents is estimated at: $19,210. There are no Operating or Maintenance Costs to report.

REQUEST FOR COMMNENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including the use of appropriate automated,