DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[Info–99–10]
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 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention. 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 Officer on (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 for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received with 60 days of this notice.

Proposed Project

1. National Surveillance of Dialysis-Associated Diseases (0920–0009)—Reinstatement—National Center for Infectious Diseases (NCID). The Hospital Infectious Program, NCID is proposing renewal of a yearly mail survey of dialysis practices and dialysis-associated diseases at U.S. outpatient hemodialysis centers. The rehabilitation of individuals in the United States who suffer from chronic renal failure has been identified as an important national priority; and since 1973, chronic hemodialysis patients have been provided financial support by the Federal Government. The Hospital Infections Program and the Hepatitis Branch, Division of Viral and Ricketsial Diseases, Centers for Disease Control and Prevention, have responsibility for formulating strategies for the control of hepatitis, bacteremia, pyrogenic reactions, and other hemodialysis-associated disease.

In order to devise such control measures, it is necessary to determine the extent to which the incidence of these dialysis-associated diseases changes over time. This request is to continue surveillance activities among chronic hemodialysis centers nationwide. In addition, once control measures are recommended it is essential that such measures be monitored to determine their effectiveness. The survey is conducted once a year by mailing it to all chronic hemodialysis centers licensed by the Health Care Financing Administration (HCFA). Dialysis practices surveyed include the use of hepatitis B vaccine in patients and staff members, whether isolation rooms are used to treat hepatitis B surface antigen-positive patients, the types of vascular access and dialyzers used, whether certain dialysis items are disinfected for reuse, and whether the dialysis center has any policy for insuring judicious use of antimicrobial agents. Among dialysis-associated diseases, the survey includes hepatitis B virus infection, antibody to hepatitis C virus, antibody to human immunodeficiency virus, pyrogenic reactions, and vancomycin-resistant enterococci. The total cost of the respondents is $128,000.

<table>
<thead>
<tr>
<th>Respondents</th>
<th>Number of respondents</th>
<th>Number of responses/ respondent</th>
<th>Avg. burden/ response (In hrs.)</th>
<th>Total response burden (In hrs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Hemodialysis Centers</td>
<td>3,200</td>
<td>1</td>
<td>1</td>
<td>3,200</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>3,200</td>
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</table>

2. Survey of Private Industry Users of Data from the National Health and Nutrition Examination Survey—NEW— The National Health and Nutrition Examination Survey (NHANES) has been conducted periodically since 1970 by the National Center for Health Statistics (NCHS), CDC. NHANES data are collected in two phases, a household
These recommendations were published by the division, the National Health and Nutrition Examination Survey (NHANES), in the Morbidity and Mortality Weekly Report of February 17, 1995. The purpose of this survey is to determine:

I. The penetration of the recommendations distribution,

II. The usefulness of the bicycle helmet recommendations,

III. How to improve the recommendations' content and format,

IV. Potential future DUIP bicycle helmet promotional activities,

V. Information needs and access points of DUIP's “customers”

Results from this research will be used to (1) assist DUIP in producing an updated version of the helmet recommendations; (2) identify new helmet promotion programmatic directions; and (3) develop future materials that meet the needs of DUIP’s “customers.”

The survey will be conducted through telephone interviews. The total cost to respondents is estimated to be $0.00.

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<thead>
<tr>
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<th>Avg burden/ response (In hrs.)</th>
<th>Total response burden (In hrs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>1,300</td>
<td>1</td>
<td>.33</td>
<td>429</td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>429</td>
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</tbody>
</table>

The survey respondents will be identified through a range of mechanisms including identifying names of public health, epidemiology, and health services research unit directors at major pharmaceutical, health care delivery organizations (including HMOs), and biotechnology companies through industry organizations and by referral. The goal is to identify both current users and non-users of the data. The survey will be voluntary and confidential. The survey will use an interview format with open-ended questions to address the proposed study objectives. Primarily qualitative survey methods will be used to evaluate the data. The total cost to respondents is estimated to be $0.00.

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<th>Total response burden (In hrs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private Industry NHANES Data Users</td>
<td>200</td>
<td>1</td>
<td>1</td>
<td>200</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>200</td>
</tr>
</tbody>
</table>
Nancy Cheal, Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–4925 Filed 2–26–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0240]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extralabel Drug Use in Animals

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, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for development of residue detection methodology for human or animal drug(s) prescribed for extra label use in animals, when the agency has determined their is reasonable probability this use may present a risk to public health due to residues exceeding a safe level.

DATES: Submit written comments on the collection of information by April 30, 1999.

ADDRESSES: 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: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910–0325—Extension)

Description: The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), (Pub. L. 103–396), amended the Federal Food, Drug, and Cosmetic Act to permit licensed veterinarians to prescribe extralabel use in animals of approved human and animal drugs. Regulations implementing provisions of AMDUCA are codified under part 530 (21 CFR part 530). A new provision under these regulations, § 530.22(b), permits FDA to establish a safe level for extralabel use in animals, of an approved human or animal drug when the agency determines there is reasonable probability that this use may present a risk to the public health. The extralabel use in animals of an approved human or animal drug that results in residues exceeding the safe level is considered an unsafe use of a drug. In conjunction with the establishment of a safe level, the new provision allows FDA to request development of an acceptable residue detection method for an analysis of residues above any safe level established under part 530. The sponsor may be willing to provide the methodology in some cases, while in others, FDA, the sponsor, and perhaps a third party, (e.g., a State agency or a professional association), may negotiate a cooperative arrangement to develop the methodology. If no acceptable analytical method is developed, the agency would be permitted to prohibit extralabel use of the drug. The respondents may be sponsors of new animal drug(s), State or Federal government, or individuals.

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

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.22(b)</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4,160</td>
<td>8,320</td>
</tr>
</tbody>
</table>

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

The estimate of the time required for this reporting requirement is based on the agency’s communication with industry. The agency recognizes that the time to develop residue detection methodology is highly variable and dependent upon the level of difficulty to a certain extent. Based on this information, FDA estimates that two methods of intermediate difficulty for one to two drugs per year would be developed.


William K. Hubbard,

Acting Deputy Commissioner for Policy.

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