Toxicological profile	NTIS Order No.	CAS No.
5. CHLORODIBENZO-P-DIOXIN (UPDATE)	PB99–121998	039227–53–7
DICHLORODIBENZO-P-DIOXIN		050585–39–2
HEPTACHLORODIBENZO-P-DIOXIN		037871–00–4
HEXACHLORODIBENZO-P-DIOXIN		034465–46–8
OCTACHLORODIBENZO-P-DIOXIN		003268–87–9
PENTACHLORODIBENZO-P-DIOXIN		036088–22–9
TRICHLORODIBENZO-P-DIOXIN		039227–58–2
TETRACHLORODIBENZO-P-DIOXIN		041903–57–5
1,2,3,4,6,7,8-HEPTACHLORODIBENZO-P-DIOXIN		035822–46–9
6. 2,4-DINITROTOLUENE (UPDATE) and 2,6-DINITROTOLUENE	PB99–122004	000121–14–2 000606–20–2
7. PHENOL (UPDATE)	PB99–122012	000108–95–2
8. SULFUR DIOXIDE	PB99–122020	007446–09–5
9. SULFUR TRIOXIDE and SULFURIC ACID	PB99–122036	007446–11–9 007664–93–9

Dated: February 22, 1999.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 99–4926 Filed 2–26–99; 8:45 am]

BILLING CODE 4163–70–P

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 Rickettsial 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.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (In hrs.)	Total response burden (In hrs.)
Chronic Hemodialysis Centers	3,200	1	1	3,200
Total				3,200

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

interview and an examination in mobile examination centers that travel throughout the country. The survey is the only source of nationally representative examination and biological specimen data for many important diseases and has often provided useful information on new technologies such as Dual Energy X-ray Absorptiometry, a method used to diagnose osteoporosis. NHANES has been extensively used by the public health and medical research communities to address a wide range of public health problems, including hypertension, diabetes, cholesterol, obesity, lead exposure, and sexually transmitted diseases. Most of our users appear to be based in traditional academic and public health settings. However, many important efforts to promote public health occur in the private sector, whether in the direct delivery of services or in the development of new treatment and diagnostic modalities. Based on inquiries received by the division, the NHANES data are used by private industry, including the pharmaceutical industry and the health care delivery industry, for a variety of purposes. However, little is known of the extent of use of the data for these industries and for the related biotechnology industries and how the data are used.

The objectives of the proposed survey are to (1) describe the extent of use of the NHANES data by the private health care delivery, pharmaceutical, and biotechnology industries, (2) describe the purpose for which the data are used by these industries, and (3) explore ways to improve the use of these data by private industry to improve the health of the population.

Although similar questions are appropriate for other NCHS administered data collection efforts, NHANES data are unique among NCHS data efforts in its reliance on biological measurements and its direct clinical relevance. This survey will focus specifically on the unique relevance of NHANES examination and biologic specimen data but will include collection of data on general awareness of NCHS data collection efforts. The results may be used to determine the feasibility of collecting data targeted to other NCHS data collection efforts.

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 $10,000.

Respondents	Number of respondents	Number of responses/ respondent	Avg burden/ response (In hrs.)	Total response burden (In hrs.)
Private Industry NHANES Data Users	200	1	1	200
Total				200

3. Evaluation of NCIPC Recommendations on Bicycle Helmet Use—Reinstatement—The National Center for Injury Prevention and Control's (NCIPC), Division of Unintentional Injury Prevention (DUIP) intends to continue to conduct a survey of 1,300 persons from its mailing lists and lists of recipients of recommendations on the use of bicycle helmets in preventing head injuries. These recommendations were published 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 ''customers.''

The study will be done by telephone.

The total cost to respondents is $0.00.

Respondents	Number of respondents	Number of responses/ respondent	Avg burden/ response (In hrs.)	Total response burden (In hrs.)
Individual	1,300	1	.33	429
Total				429

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 byApril 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 permits 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 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

[1] 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.

Dated: February 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–4875 Filed 2–26–99; 8:45 am]

BILLING CODE 4160–01–F