

comments should be received within 30 days of this notice.

Proposed Project: National Vital Statistics Report Forms (OMB No. 0920-0213)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background

The National Vital Statistics Report Forms (0920-0213) is an approved collection of the compilation of national vital statistics. This collection dates back to the beginning of the 20th century and has been conducted since 1960 by the Division of Vital Statistics of the National Center for Health

Statistics, CDC. The collection of the data is authorized by 42 U.S.C. 242k. The National Vital Statistics Report forms provide counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces. Similar data have been published since 1937 and are the sole source of these data at the national level. The data are used by the Department of Health and Human Services and by other government, academic, and private research and commercial organizations in tracking changes in trends of vital events.

Respondents for the Monthly Vital Statistics Report Form (CDC 64.146) are

registration officials in each State and Territory, the District of Columbia, and New York City. In addition, 60 local (county) officials in New Mexico who record marriages occurring and divorces and annulments granted in each county of New Mexico will use this Form. The data are routinely available in each reporting office as a by-product of ongoing activities. This form is designed to collect counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces immediately following the month of occurrence. There are no costs to respondents.

Respondents to the form: Monthly Vital Statistics Report (CDC 64.146)	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hours)
State and Territory registration officials	57	12	12/60
New Mexico County officials	60	12	6/60

The Annual Marriage and Divorce Statistical Report Form (CDC 64.147) collects final annual counts of marriages and divorces by month for the United States and for each State. The statistical counts requested on this form differ from provisional estimates obtained on the Monthly Vital Statistics Report Form in that they represent complete and final counts of marriages, divorces, and annulments occurring during the months of the prior year. These final counts are usually available from State

or county officials about eight months after the end of the data year. The data are widely used by government, academic, private research, and commercial organizations in tracking changes in trends of family formation and dissolution.

Respondents for the Annual Marriage and Divorce Statistical Report Form are registration officials in each State, the District of Columbia, New York City, Guam, Puerto Rico, Virgin Islands, Northern Marianas, and American Samoa. In addition, counts of marriages

will be collected from individual counties in New Mexico, and counts of divorces will be collected from individual counties in California, Colorado, Indiana, Louisiana, New Mexico, and the boroughs of New York City due to a lack of centralized complete collections in these registration areas. The data are routinely available in each reporting office as a by-product of ongoing activities. The total estimated annualized burden for this data collection is 410 hours.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hours)
State/Territory/City registration officials	56	1	30/60
County/Borough officials	348	1	30/60

Dated: February 25, 2003.

Thomas A. Bartenfeld,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0303]

Agency Information Collection Activities; Announcement of OMB Approval; Guidance for Industry on Formal Dispute Resolutions; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Formal Dispute Resolutions; Appeals Above the

Division Level" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of October 16, 2002 (67 FR 63929), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

number. OMB has now approved the information collection and has assigned OMB control number 0910-0430. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 26, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-4976 Filed 3-3-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93D-0398]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: "Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by April 3, 2003.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: "Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora"

In the *Federal Register* of December 27, 2001 (66 FR 66910), FDA published a 60-day notice that requested comments to the proposed collection of information. In response, the agency received two submissions containing several comments. The commenters generally supported the pathway approach outlined in the draft guidance. The comments centered on the type of information that needs to be included and the endpoints that need to be addressed. Based on suggestions contained in the comments, this final guidance will eliminate the endpoint of metabolic activity of the intestinal flora (which was proposed in the draft guidance) and will consider human data to have more weight as evidence of adverse effect on the intestinal flora, when human data is available.

Sponsors of new animal drugs must meet certain statutory requirements for

new animal drug approval under section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b). Among other things, the sponsor must demonstrate that the use of the drug is safe. Thus, when the Center for Veterinary Medicine (CVM) reviews new animal drug applications for drugs that will be used in food-producing animals, it must determine whether residues of the drug that may remain in human food derived from those animals would be harmful to humans. One possible harmful effect of residues of antimicrobial drugs that CVM considers in this determination is the possible effect of residues on human intestinal flora.

This guidance document describes the pathway approach for assessing such effects. An assessment of the safety of antimicrobial drug residues in food is a major issue that we recommend be addressed by the sponsor of a new animal drug. For residues determined to have no antimicrobial activity against representatives of the human intestinal flora, an acceptable daily intake (ADI) is recommended to be calculated based on traditional toxicological studies. The burden hours required are reported and approved under OMB control number 0910-0032. However, the guidance recommends that additional information be provided for certain drugs if an assessment of microbiological safety determines that a new animal drug produces residues in foods that are microbiologically active in the human colon. The likely respondents to this collection of information are sponsors of antimicrobial new animal drugs that will be used in food-producing animals. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Guidance	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Assessments (microbiological studies) of safety of antimicrobial drug residues that are microbiologically active in the human colon	5	1	5	14,110	70,550

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 of this document resulted from discussions with sponsors of new animal drugs. The estimated burden includes studies, analysis of data, and writing the assessment. The number of respondents provided is based on current experience, however, the number may change in the future.

Dated: February 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.