factors for physical, non-physical, and electronic WPV in teachers and paraprofessionals in Pennsylvania; (3) Measure the impact of WPV on job satisfaction and quality of life. These goals are solely based on the State of Pennsylvania and are not based on a nation wide study.

NIOSH is proposing to conduct a population-based, cross-sectional survey among teachers and paraprofessionals in the State of Pennsylvania. Paper-and-pencil surveys will be mailed to potential participants through the Pittsburgh Federation of Teachers (PFT), Philadelphia Federation of Teachers (PA–AFT), and the Pennsylvania State Education Association (PSEA). Since approximately 90% of teachers and 65% of paraprofessionals in the State of Pennsylvania hold membership in one of these three unions and no known State-wide database exists that includes both teachers and paraprofessionals, a sample of eligible participants will be drawn using State-based union records.

A stratified random sample will be drawn to ensure representativeness on important dimensions such as gender of participant and urban-rural status of the school district. In conjunction with each participating union, study packets consisting of an introduction letter, paper-and-pencil survey, and non-response form will be mailed to eligible participant's home addresses. The questionnaire is a paper-and-pencil survey and provides information on the following categories: demographics, occupation, physical assault characteristics, non-physical assault characteristics, electronic aggression characteristics, job satisfaction, and quality of life.

The sample size for the cross-sectional survey is estimated to be approximately 5,000 teachers and paraprofessionals. This estimate is based on the number of reported teachers and paraprofessionals represented by the three unions participating in this study and on an 80% response rate that is comparable to the response rate of previously conducted surveys in similar populations. Pilot test data demonstrates that respondents should take approximately 30 minutes to complete the paper-and-pencil survey, resulting in an annualized burden estimate of 2,500 hours. Participation in the study is completely voluntary.

This survey will also utilize the skills and time of a variety of union office and administrative staff for the preparation of the survey packets. The exact number of administrative staff utilized at each union location, as well as the additional work demands placed on them has yet to be determined, though our best guess is 13 individuals. It is estimated that three office support staff from the Pittsburgh Federation of Teachers, six from the Pennsylvania State Education Association, and four from the Philadelphia Federation of Teachers will be needed for a grand total of 13 support staff personnel. Additional work activities could include: Preparation of the sampling frame database and non-respondent database, printing of mailing labels, affixation of mailing labels onto survey packets, and e-mail and/or phone communication with NIOSH. For each mailing, we estimate that each of the 13 administration assistants will dedicate two hours to the mailing. So, for each mailing, a grand total of 26 hours will be burdened. There will be three separate mailings for a grand total burden of 78 burden hours.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 2,578.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|
| Elementary and Secondary School Employees | 5,000 | 1 | 30/60 |
| Office & Administrative Support Occupations | 13 | 3 | 2 |

Dated: October 19, 2009.

**Maryam Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E9–25649 Filed 10–23–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0512]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

**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 including each proposed extension of a collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for antimicrobial animal drug distribution as required by Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA).

**DATES:** Submit written or electronic comments on the collection of information by December 28, 2009.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

**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 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 these topics: (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.

**Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008—Federal Food, Drug, and Cosmetic Act, Section 512(1)(3) (OMB Control Number 0910–NEW)**

Section 105 of ADUFA amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form, (2) quantities distributed domestically and quantities exported and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

The first report must be submitted not later than March 31, 2010. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. The reports required under section 105 of ADUFA are required to be separate from periodic drug experience reports that are required under 21 CFR 514.80(b)(4) (OMB Control No. 0910–0284).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| FD&C Act Section 512(1)(3) | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Capital Cost |
|---|---|---|---|---|---|---|
| Annual Reports for Sponsors with Active Applications | 29 | 6.7 | 194 | 80 | 15,520 | $107,880 |
| Annual Reports for Sponsors with Inactive Applications | 23 | 4.0 | 92 | 1 | 92 | |
| Total | | | | | 15,612 | $107,880 |

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| FD&C Act Section 512(1)(3) | No. of Respondents | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| All Applicants | 34 | 1 | 34 | 2 | 68 |
| Total | | | | | 68 |

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

The reporting burden estimates, including the total number of annual responses, are based on the number of sponsors and approved applications for antimicrobial drug products in food-producing animals. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

The agency arrived at the estimates for reporting as follows: There are 34 sponsors with approved applications for antimicrobial drugs for food-producing animals. There are 29 animal drug manufacturers with 194 approved applications for antimicrobial drugs for food-producing animals for which the drugs are being actively marketed (active applications). Additionally, there are 93 approved applications for antimicrobial drugs for food-producing animals for which the drugs are not being marketed (inactive applications), owned by 23 animal drug manufacturers.

Regarding the reporting burden associated with the collection of information, FDA believes that the large majority of the burden will be incurred by industry in the first year in which reporting is required to design a report that meets the requirements of section 512(l)(3) of the act. The agency has estimated this burden at 80 hours per applicant with active applications. The agency has factored into this estimate the time it will take industry to identify and locate the necessary information within existing records, and to develop a report that complies with section 512(l)(3) of the act. Once this has been accomplished, FDA believes that the process for producing reports in subsequent years will essentially be automated, and that it will take

approximately 3 hours to run a report that satisfies the act's requirements. For sponsors of approved applications that are inactive (i.e., the approved drug is not being marketed), the sponsor would only have to submit a report stating that the drug is not being marketed, which FDA estimates will take approximately 1 hour.

FDA has developed a form to report the information required by section 512(l)(3) of the act. FDA plans to make the form available to animal drug manufacturers through FDA's website however, use of the form would be entirely voluntary. The form contains various fields for information, including the drug manufacturer's name, new animal drug approval number, active ingredient name, National Drug Code number, container size, potency, and the number of units sold by month.

The animal drug manufacturers can meet the statutory requirements by submitting their information in paper format using the FDA-provided form, one of their own designs, or by designing their own electronic form whose results could be submitted to the agency on a compact disc or on paper. The cost to animal drug sponsors for gathering the necessary information for report design and preparation or for completing FDA's form in the first year of reporting is $107,880 (29 active sponsors times 80 hours times $46.50 per hour = $107,880). This is a one-time cost for a computer or mathematic employees to design and prepare a report that satisfies the statutory requirements of section 512(l)(3) of the act.[1] For subsequent years, the preparation of the report should take approximately 3 hours. Thus, the total cost in subsequent years would be $139.50.

Regarding the recordkeeping burden associated with this collection of information, FDA believes that most of the necessary information for the annual report required to be submitted under section 512(l)(3) of the act is already collected and maintained by animal drug manufacturers under existing requirements.

Animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDA's current good manufacturing practice regulations under § 211.196 (21 CFR § 211.96) (OMB Control No. 0910–0139), and to comply with regulations for periodic drug experience reports under § 514.80(b)(4)(i) (21 CFR § 514.80(b)(4)(i)) (OMB Control No. 0910–0284) of FDA regulations. Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and additional equipment necessary to collect and maintain the necessary records, and to make reports.

Section 512(l)(3) of the act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. Under § 211.196 (OMB Control No. 0910–0139), manufacturers currently are required to maintain distribution records that include the dosage form and date the drug is distributed. Additionally, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of their usual and customary practice. However, FDA estimates additional hourly burden required by section 512(l)(3) of the Act as shown in table 2 of this document.

Dated: October 16, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–25671 Filed 10–23–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Parent-Child Assistance Program (P–CAP) in the Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence—New**

Since 2001, SAMHSA's Center for Substance Abuse Prevention has been operating a Fetal Alcohol Spectrum Disorder (FASD) Center of Excellence which addresses FASD mainly by providing trainings and technical assistance; and developing and supporting systems of care that respond to FASD using effective evidence based practices and interventions.

Currently the integration of evidence-based practices into service delivery organizations is being accomplished through subcontracts. One such intervention which integrates prevention strategies into service delivery organizations is the Parent-Child Assistance Program (P–CAP) targeting pregnant or postpartum women. The P–CAP program uses the following 11 data collection tools.

DESCRIPTION OF INSTRUMENTS/ACTIVITY FOR PARENT-CHILD ASSISTANCE PROGRAM (P–CAP)

| Instrument/Activity | Description |
|---|---|
| At Baseline/Enrollment: | |
| CRSQ | The Community Referral Screening Questionnaire (CRSQ) is a screening form administered to individuals referred to P–CAP. The purpose of the form is to determine eligibility for enrollment in P–CAP. |
| ASI—Part A | The Addiction Severity Index (ASI) Part A is an intake interview administered at client enrollment. The ASI Part A includes questions about past 30-day alcohol use, lifetime use, age at first use, month and year of last use, range of use (T–ACE), and use during pregnancy, thereby providing a thorough assessment of alcohol consumption. |
| ASI—Part B & Twin | The Addiction Severity Index (ASI) Part B is an intake interview administered as soon as possible after the target child birth. The ASI Part B includes questions about the target child at birth and alcohol use during the pregnancy. If the target birth is of twins then the Twins Addendum form is administered. |

[1] BLS Occupation Employment and Wages, May 2006, by occupation, for all industries (*http://www.bls.gov*). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15–0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits.