In January 2009, FDA held a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to address the safety and efficacy of propoxyphene and propoxyphene combination products for the treatment of mild to moderate pain. The committee members voted 14 to 12 against the continued marketing of propoxyphene products but noted that additional information about the drug's cardiac effects would be relevant in weighing its risks and benefits. Using authority under the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), FDA required Xanodyne to conduct a safety study of the effects of propoxyphene on the heart at higher than recommended doses.

Before proceeding with the cardiac safety study, the company first conducted a study on healthy volunteers to determine an appropriate dose. In this study, the healthy volunteers in one group were given a total daily dose of 600 mg of propoxyphene (the maximum approved dose), and volunteers in the second group were given a total daily dose of 900 mg (a dose higher than recommended in product labeling). The results showed that there were significant changes to the electrical activity of the heart (prolonged PR interval, widened QRS complex, and prolonged QT interval), at both the 600 and 900 mg doses. These changes, which can be seen on an electrocardiogram, can increase the risk for serious abnormal heart rhythms. In light of these new scientific findings, CDER determined the postmarketing safety signals for this drug have taken on new importance, and the overall balance of risk and benefit can no longer be considered favorable. Memoranda explaining CDER's determination are available on FDA's Web site and will be placed in Docket No. FDA–2014–N–0199 (Refs. 1 and 2).

On November 19, 2010, FDA issued a Drug Safety Communication recommending against the continued prescription and use of propoxyphene drug products. This recommendation was based on all available data, including the new data showing that when propoxyphene is taken at therapeutic doses, it can cause significant changes to the electrical activity of the heart. FDA has concluded that this safety risk outweighs propoxyphene's benefits for pain relief at recommended doses. Based on this information, FDA asked the manufacturers of currently marketed propoxyphene products to voluntarily remove their products from the market.

Therefore, based on all available data, notice is given to the holders of the approved applications listed in Table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the FD&C Act, withdrawing approval of the applications, amendments, and supplements upon the grounds that scientific data show the listed drugs are unsafe under the conditions of use for which they were approved.

II. Hearing Procedures

In accordance with section 505(e) of the FD&C Act, the applicants are hereby provided an opportunity to request a hearing to show why approval of the applications listed in Table 1 should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing must file the following: (1) A written notice of participation and request for hearing (see **DATES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing to resolve (see **DATES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under the authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

III. References

FDA has placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). They may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Memorandum to Dr. Woodcock: Recommendation on a Regulatory Decision for Propoxyphene-Containing Products (November 18, 2010, Hertz and Avigan); *http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM234349.pdf.*

2. Memorandum to Dr. Woodcock on Propoxyphene-Containing Products (November 18, 2010, Rappaport); *http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM234340.pdf.*

Dated: March 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05062 Filed 3–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services

Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Data Collection Tool for Rural Health Community-Based Grant Programs

OMB No.: 0915–0319—Revision

Abstract: There are currently five rural health grant programs that operate under the authority of section 330A of the Public Health Service (PHS) Act. These programs include: (1) Rural Health Care Services Outreach Grant Program (Outreach); (2) Rural Health Network Development Grant Program (Network Development); (3) Small Healthcare Provider Quality Grant Program (Quality); (4) Delta States Rural Development Network Grant Program (Delta); and (5) Rural Health Network Development Planning Grant Program (Network Planning). These grants are to provide expanded delivery of health care services in rural areas, for the planning and implementation of integrated health care networks in rural areas, and for the planning and implementation of quality improvement and workforce activities. In general, the grants may be used to expand access, coordinate, and improve the quality of essential health care services and enhance the delivery of health care in rural areas.

Need and Proposed Use of the Information: For these programs, performance measures were drafted to provide data useful to the programs and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to ORHP, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for all six programs. All measures will speak to the ORHP's progress toward meeting the goals set.

Likely Respondents: Award recipients of the programs under the section 330A of the Public Health Service Act.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Grant Program Measures	71	1	71	2	142
Rural Health Network Development Grant Program Measures	20	1	20	5	100
Delta States Rural Development Network Grant Program	12	1	12	6	72
Small Health Care Provider Quality Improvement Grant Program	30	2	60	10	600
Rural Health Network Development Planning Grant Program Measures	21	1	21	1	21
Total	154	.....	184	.....	935

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: February 28, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–05137 Filed 3–7–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.