

amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 20, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013-20615 Filed 8-22-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0835]

Withdrawal of Approval of New Animal Drug Applications; Diethylcarbamazine; Nicarbazine; Penicillin; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) at the sponsors' request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 3, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843, email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health Corp., 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660 has requested that FDA withdraw approval of NADA 098-371 for use of nicarbazine, penicillin, and roxarsone in 3-way, combination drug Type C medicated feeds for broiler chickens and NADA 098-374 for use of nicarbazine and penicillin in 2-way, combination drug Type C medicated feeds for broiler chickens because the products are no longer manufactured or marketed.

R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 has requested that FDA withdraw approval of NADA 123-116 for Diethylcarbamazine Citrate Capsules used in dogs for the prevention of heartworm disease because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance

with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 098-371, NADA 098-374, and NADA 123-116, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these applications.

Dated: August 19, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013-20541 Filed 8-22-13; 8:45 am]

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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: Combating Autism Act Initiative Evaluation (OMB No. 0915-0335 [Revision])

Abstract: In response to the growing need for research and resources devoted to autism spectrum disorders (ASD) and other developmental disabilities (DD), the U.S. Congress passed the Combating Autism Act (CAA) in 2006. The Act included funding for the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions, train health care professionals to screen for, diagnose or rule out, and provide evidence-based interventions for ASD and other DD. In 2011, the Combating Autism Reauthorization Act (CARA) was signed into law, reauthorizing funding for the CAA's programs for an additional 3 years at the existing funding levels. Through the CARA, HRSA is tasked with increasing awareness of ASD and other DD, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training health care professionals in the use of valid and reliable screening and diagnostic tools.

Need and Proposed Use of the Information: HRSA's activities under the CARA legislation are delegated to the Maternal and Child Health Bureau (MCHB), which is implementing the Combating Autism Act Initiative (CAAI) in response to the legislative mandate. The purpose of this evaluation is to design and implement an evaluation to assess the effectiveness of MCHB's activities in meeting the goals and objectives of the CAAI, and to provide sufficient data to inform MCHB and the Congress as to the utility of the grant programs funded under the Initiative. The evaluation will focus on indicators related to: (1) Increasing awareness of ASD and other DD among health care providers, other MCH professionals, and the general public; (2) reducing barriers to screening and diagnosis; (3) supporting research on evidence-based interventions; (4) promoting the development of evidence-based guidelines and tested/validated intervention tools; (5) training professionals; and (6) building capacity for systems of services in states.

Likely Respondents: Grantees funded by HRSA under the CAAI will be the respondents for this data collection activity. The programs to be evaluated are listed below.

1. Training Programs

- Leadership Education in Neurodevelopmental Disabilities (LEND) training programs with forty-three grantees;
- Developmental Behavioral Pediatrics (DBP) training programs with ten grantees; and
- A National Combating Autism Interdisciplinary Training Resource Center grantee.

2. Research Networks Program

- Two Autism Intervention Research Networks that focus on intervention research, guideline development, and information dissemination; and
- 20 R40 Maternal and Child Health (MCH) Autism Intervention Research Program grantees that support research on evidence-based practices for interventions to improve the health and well-being of children and adolescents with ASD and other DD.

3. State Implementation Program Grants for Improving Services for Children and Youth With Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD)

- 18 grantees will implement state autism plans and develop models for improving the system of care for children and youth with ASD and other DD;
- 4 grantees will design state plans for improving the system for children and youth with ASD and other DDs; and
- A State Public Health Coordinating Resource Center grantee.

The data gathered through this evaluation will be used to:

1. Evaluate the grantees' performance in achieving the objectives of the CAAI during the three year grant period;
2. Assess the short- and intermediate-term impacts of the grant programs on children and families affected by ASD and other DD; and
3. Measure the CAAI outputs and outcomes for the report to Congress.

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 ICR are summarized in the table below. The Principal Investigator or Project Director from each grant program will be interviewed. The questionnaires for the Research Programs and the State Implementation grant programs will be completed by each Principal Investigator/Project Director.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Grant program/form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
LEND Interview Protocol	43	1	43	1	43
DBP Interview Protocol	10	1	10	1	10
State Implementation Program Interview Protocol	22	1	22	1	22
State Implementation Program Questionnaire	22	1	22	.75	16.5
Research Program Interview Protocol (Networks only)	2	1	2	1	2
Research Program Questionnaire	20	1	20	.75	15
Resource Centers Interview Protocol	2	1	2	1	2
Total	121		121		110.50

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: August 16, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-20544 Filed 8-22-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Date and Time: September 9, 2013 (8:30 a.m.–5:00 p.m.), September 10, 2013 (8:30 a.m.–5:00 p.m.).

Place: Combined In-Person and Webinar Format, Health Resources and Services Administration, U.S. Department of Health and Human Services, 5600 Fishers Lane, Rockville, Maryland 20852, Rooms 18-63.

Status: The meeting will be open to the public.

Purpose: The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs.

Agenda: The meeting will begin with opening comments from the Health Resources and Services Administration (HRSA) senior officials and updates on HRSA-specific programs related to the physician workforce. The Council is expected to hear from subject matter experts on new health care delivery