DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0002]
Withdrawal of Approval of New Animal Drug Applications; Arsanilic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) for an arsanilic acid Type A medicated article at the sponsor’s request because the product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 6, 2013.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234 has requested that FDA withdraw approval of NADA 008–019 for PRO–GEN (arsanilic acid) Type A medicated article because the product, used to manufacture Type B and Type C medicated feeds, 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(21 CFR 514.116), notice is given that approval of NADA 008–019, and all supplements and amendments thereto, is hereby withdrawn.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 voluntary withdrawal of approval of this application.

Dated: November 20, 2013.

Bernadette Dunahm,
Director, Center for Veterinary Medicine.

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a stakeholder meeting hosted by the NIH Scientific Management Review Board (SMRB). The SMRB’s Working Group on Approaches to Assess the Value of Biomedical Research Supported by NIH will present their findings and conclusions regarding optimal approaches to assessing the value of biomedical research supported by the NIH.

The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or eliminating or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the SMRB is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board (SMRB).
Date: December 18, 2013.
Time: 10:00 a.m. to 12:00 p.m. (EST).
Agenda: The teleconference will focus on the findings and recommendations of the Working Group on Approaches to Assess the Value of Biomedical Research Supported by NIH. The full Board will review and vote on the draft report from the Working Group.

Interested persons are invited to attend the public portion of the meeting. Attendance by members of the public will be limited to 50 people; in the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

Dated: November 20, 2013.

Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

[FR Doc. 2013–28266 Filed 11–25–13; 8:45 am]
BILLING CODE 4184–22–P