FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product VERAFLOX (pradofloxacin). VERAFLOX is indicated for treatment of skin infections in cats caused by susceptible strains of *Pasteurella multocide, Streptococcus canis, Staphylococcus aureus, Staphylococcus felis,* and *Staphylococcus pseudintermedius.* Subsequent to this approval, the USPTO received a patent term restoration application for VERAFLOX (U.S. Patent No. 6,323,213) from Bayer Animal Health GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 26, 2014, FDA advised the USPTO that this animal drug product had undergone a regulatory review period and that the approval of VERAFLOX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VERAFLOX is 3,285 days. Of this time, 3,235 days occurred during the testing phase of the regulatory review period, while 50 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the FD&C Act (21 U.S.C. 355(i)) became effective:* November 12, 2003. The applicant claims July 31, 2002, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was November 12, 2003, which was the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* September 19, 2012. FDA has verified the applicant's claim that the new animal drug Application (NADA) for VERAFLOX (NADA 141–344) was submitted on September 19, 2012.

3. *The date the application was approved:* November 7, 2012. FDA has verified the applicant's claim that NADA 141–344 was approved on November 7, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,901 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31099 Filed 12–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Viral Hepatitis Action Plan—Community Stakeholder Activities Request for Information

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is seeking public input from state and local governments, community based organizations, academic institutions, professional organizations, advocacy groups, private industry, and other non-federal stakeholders on activities undertaken in 2014–2015 in support of the goals of the national Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis.

DATES: All responses must be received at the address provided below, no later than 5:00 p.m. ET on February 8, 2016.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *Corinna.Dan@hhs.gov.* Written responses should be addressed to: U.S. Department of Health and Human Services, 200 Independence Ave. SW., Room 443H, Washington, DC 20201. Attention: VHAP—2015RFI

FOR FURTHER INFORMATION CONTACT: Corinna Dan, RN, MPH, Office of HIV/AIDS and Infectious Disease Policy, (202) 401–9581.

SUPPLEMENTARY INFORMATION: The updated comprehensive national action plan, *Combating the Silent Epidemic of*

Viral Hepatitis: Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis 2014–2016, details more than 150 actions to be undertaken between 2014 and 2016 by 20 federal agencies and offices from across the U.S. Departments of Health and Human Services (HHS), Housing and Urban Development (HUD), Justice (DOJ), and Veterans Affairs (VA). While the Viral Hepatitis Action Plan describes efforts to be undertaken by federal stakeholders, many of the successes our nation has seen in the fight against viral hepatitis have resulted from non-federal efforts including those of health departments, academic researchers, community-based organizations, professional organizations, education and advocacy groups, private industry, and other stakeholders. The Viral Hepatitis Action Plan provides a framework around which all stakeholders can engage to strengthen the nation's response to viral hepatitis and envisions active involvement of and innovation by a broad mix of partners from both public and private sectors.

The updated Action Plan describes four main goals to be achieved by 2020:

- Increase in the proportion of persons who are aware of their hepatitis B virus (HBV) infection, from 33% to 66%.
- Increase in the proportion of persons who are aware of their hepatitis C virus (HCV) infection, from 45% to 66%.
- Reduce by 25% the number of new cases of HCV infection.
- Eliminate mother-to-child transmission of HBV.

This request for information seeks public comment on several key areas with respect to non-federal efforts undertaken throughout calendar years 2014–2015 that are consistent with the four main goals of the Viral Hepatitis Action Plan. Comments are sought on (but not limited to) the following:

1. Describe the type of organization or group with which you are affiliated (*e.g.*, advocacy, private industry, health care, local, or state government, etc.).

2. What is the most significant need your community/clients experience with respect to combating viral hepatitis?

3. What activities conducted in 2014 and 2015 demonstrated the greatest advances toward reaching the goals of the Viral Hepatitis Action Plan? Responses are invited (but not limited to) viral hepatitis activities in the following areas:

a. Raising awareness about viral hepatitis among the general public, specific targeted populations, and/or community leaders;

b. Training and/or increasing capacity of health care providers to prevent, diagnose, treat viral hepatitis;

c. Developing strategies to promote timely viral hepatitis diagnosis and linkage to care;

d. Developing/implementing clinical decision support tools and/or improved protocols in clinical settings that improve viral hepatitis health outcomes;

e. Implementing strategies to educate women of child-bearing age and high risk groups about mother-to-infant transmission of hepatitis B;

f. Reaching people who inject drugs with viral hepatitis information and services;

g. Improving viral hepatitis infection prevention awareness and initiatives in medical settings;

h. Developing strategies to foster stakeholder collaboration and sustainable programs; and

i. Other (please specify).

4. Please include relevant information such as the dates of implementation; names of collaborating organizational partners; related Action Plan goal(s); geographic area and populations served, quantitative findings and outcomes such as number of tests done, proportion of positives identified; and links to online tools, resources, and publications.

Please limit responses to four pages, single-sided, double spaced, 10 point font.

Selected activities will be compiled and made available to federal partners, stakeholders, and the public in order to foster further expansion, innovation, and collaboration toward achieving the goals of the Viral Hepatitis Action Plan. Reponses to this RFI will also be used to inform future HHS strategic planning and implementation.

Dated: December 7, 2015.

Ronald O. Valdiserri,

Deputy Assistant Secretary for Health, Infectious Diseases, Office of the Assistant Secretary for Health.

[FR Doc. 2015–31131 Filed 12–9–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Girija Dasmahapatra, Ph.D., Virginia Commonwealth University: Based on the report of an inquiry conducted by Virginia Commonwealth University (VCU), the willingness of the Respondent to settle this matter, and analysis conducted by ORI in its oversight review, ORI found that Dr. Girija Dasmahapatra, former Instructor, Department of Internal Medicine, VCU, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA063753, R01 CA093738, and R01 CA100866.

ORI found that false data were included in the following eleven (11) publications:

- *Blood* 107:232–40, 2006 Jan (hereafter referred to as ''*Blood* 2006'')
- *Blood* 115:4478–87, 2010 Jun 3 (hereafter referred to as ''*Blood* 2010'')
- *British Journal of Haematology* 161:43–56, 2013 Apr (hereafter referred to as ''*BJH* 2013'')
- *Cancer Biology & Therapy* 8:808–19, 2009 May (hereafter referred to as ''*CBT* 2009'')
- *Clinical Cancer Research* 13:4280–90, 2007 Jul (hereafter referred to as ''*CCR* 2007'')
- *Leukemia* 19:1579–89, 2005 Sep (hereafter referred to as ''*Leuk* 2005'')
- *Leukemia Research* 30:1263–1272, 2006 (hereafter referred to as ''*LR* 2006'')
- *Molecular Cancer Therapeutics* 10:1686–97, 2011 Sep (hereafter referred to as ''*MCT* 2011'')
- *Molecular Cancer Therapeutics* 11:1122–32, 2012 May (hereafter referred to as ''*MCT* 2012'')
- *Molecular Cancer Therapeutics* 13:2886–97, 2014 Dec (hereafter referred to as ''*MCT* 2014'')
- *Molecular Pharmacology* 69:288–98, 2006 Jan (hereafter referred to as ''*MP* 2006'')

ORI found that Respondent falsified and/or fabricated data by reporting the results of Western blot experiments and mouse imaging experiments that examined interactions between multiple histone deacetylase and/or proteasome inhibitors in several cancer models. Specifically, Respondent duplicated, reused, and/or relabeled Western blot panels and mouse images and claimed they represented different controls and/or experimental results in:

- *Blood* 2006, Figures 2A and 2B (Tubulin), 2C (c-Jun & Tubulin), and 3E and 3F (Tubulin)
- *Blood* 2010, Figures 4A and 4C (JNK & Tubulin)
- *BJH* 2013, Figures 2A and 6B (Tubulin)
- *CBT* 2009, Figure 4B (Actin)
- *CCR* 2007, Figures 3B (PARP) and 6A (Tubulin)