Dated: December 18, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–30027 Filed 12–23–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1461]

Rare Pediatric Disease Priority Review Vouchers; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of availability (NOA) that appeared in the **Federal Register** of November 17, 2014. In the NOA, FDA requested comments on the Agency's implementation of the Rare Pediatric Disease Priority Review Vouchers Program. This action will allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the NOA published November 17, 2014 (79 FR 68451). Submit either electronic or written comments by February 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of Orphan Products Development, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office that will be processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Henry Startzman III, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993–0002, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 17, 2014, FDA published a NOA with a 60-day comment period to request comments on FDA's implementation of the Rare Pediatric Disease Priority Review Vouchers Draft Guidance. Comments on the draft guidance will inform FDA's drafting of its final guidance for this program.

The Agency has recognized a discrepancy between the 90-day comment period included in the draft guidance and the 60-day comment period written in the November 17, 2014, NOA. Thus, it is publishing this NOA to extend the comment period cited in the previous NOA by 30 days.

The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying drafting of the final guidance on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: *December 18, 2014.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30154 Filed 12–23–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 23, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Feed Directive—21 CFR 558 (OMB Control Number 0910–0363)—(Extension)

With the passage of the Animal Drug Availability Act of 1996 (Public Law 104–250), Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) was tailored to the unique circumstances

relating to the distribution of medicated feeds. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed, and records must be maintained of the distribution and feeding (under the professional supervision of a licensed veterinarian) of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

On December 12, 2013, FDA published a proposed rule in the **Federal Register** (78 FR 75515), intended to improve the efficiency of FDA's VFD program. The provisions included in the proposed rule were based on stakeholder input received in response to solicitations for public comment, including an advance notice of proposed rulemaking on March 29, 2010 (75 FR 15387), and draft text of proposed amendments to the current VFD regulations on April 13, 2012 (77 FR 22247).

In the **Federal Register** of September 25, 2014 (79 FR 57558), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but it did not respond to any of the four collection of information topics solicited in the notice and therefore is not discussed in this document. At the same time, since publication of the 60-day notice, the burden for this information collection has been revised to reflect an update in the number of veterinarians, producers, and distributors, as well as updated cost burden information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(d)(1)(i) through (d)(1)(iii): A distributor must notify FDA prior to the first time it distributes a VFD drug.	300	1	300	.25 (15 minutes)	75
558.6(d)(1)(iv): A distributor must notify FDA within 30 days of any change in ownership, business name, or business address.	20	1	20	.25 (15 minutes)	5
514.1(b)(9): Sponsor submits 3 copies of VFD with new drug application.	1	1	1	3	3
Total					83

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(c)(1) through (c)(4): Filing of VFD copies by veterinarians and producers [2].	13,050	114.9	1,500,000	.0167 (1 minute)	25,050
558.6(e)(1) through (e)(4): Filing of VFD copies by distributors only [3].	1,376	545.1	750,000	.0167 (1 minute)	12,525
Total	14,426		2,250,000		37,575

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

[2] The same recordkeeping requirement for distributors is listed in two separate sections of the codified; therefore, we have listed distributors separately (in reference to 558.6(e)(1) through (e)(4)) in order to avoid double counting their recordkeeping requirement.

[3] Distributors may receive an acknowledgement letter in lieu of a VFD when consigning VFD feed to another distributor (please see table 3.). Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(a)(3) through (a)(5): Veterinarian issues VFD.	3,050	246	750,000	0.125 (7 minutes)	93,750
558.6(d)(2): Acknowledgement letter generation [2]	[2] 1,000	5	5,000	0.125 (7 minutes)	625
Total					94,375

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

[2] 1,000 VFD distributors (of the 1,376 total distributors) multiplied by 5 disclosures per distributor equals 5,000 annual acknowledgement letters, multiplied by 0.125 hours equals 625 hours annually.

The estimate of time required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30157 Filed 12–23–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2104]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Ebola Zaire Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for two in vitro diagnostic devices for detection of the Ebola Zaire virus. FDA is issuing these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the September 22, 2006, determination by then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security. On the basis of such determination, the Secretary of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorizations are effective as of October 10, 2014.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Office of Counterterrorism and Emerging Threats, and Acting Deputy Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the CDC (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.