in the **Federal Register** of December 8, 2014. In the notice, FDA requested that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Food Advisory Committee (the Committee) for the Center for Food Safety and Applied Nutrition (CFSAN) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the Committee. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit letters of interests and nominations.

DATES: FDA is extending the closing date in the notice published December 8, 2014 (79 FR 72690). Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by February 27, 2015. Concurrently, nomination materials for prospective candidates should be sent to FDA by February 27, 2015.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Karen Strambler (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Karen Strambler, Office of Regulations, Policy, and Social Science, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Rm. 1C–016, College Park, MD 20740, 240–402–2589, *karen.strambler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. CFSAN Advisory Committee, Food Advisory Committee

The Committee reviews and evaluates emerging food safety, nutrition and other food- or cosmetic-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues; (2) the safety of food ingredients and new foods; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current curriculum vitae. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, and men, members of all racial and ethnic groups and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: *January 26, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01881 Filed 1–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0175]

Determination That LYMPHAZURIN (Isosulfan Blue) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993–0002, 301–796–5418, *Amy.Hopkins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as

the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 018310 for LYMPHAZURIN (isosulfan blue) Injectable in the **Federal Register** of December 5, 2014 (79 FR 72186) and NDA 020151 for EFFEXOR (venlafaxine HCl) Tablets in the **Federal Register** of July 19, 2013 (78 FR 43210).)

Application No.	Drug	Applicant
NDA 018310	LYMPHAZURIN (isosulfan blue) Injectable; Injection, 1%	Covidien, 60 Middletown Ave., North Haven, CT 06473.
NDA 019966	TEMOVATE (clobetasol propionate) Solution; Topical, 0.05%.	Fougera Pharmaceuticals Inc., 1 Health Plaza, Bldg. 434, East Hanover, NJ 07936.
NDA 020151	EFFEXOR (venlafaxine hydrochloride (HCl)) Tablet; Oral, Equivalent to (EQ) 12.5 milligram (mg) Base; EQ 25 mg Base; EQ 37.5 mg Base; EQ 50 mg Base; EQ 75 mg Base; EQ 100 mg Base.	Wyeth Pharmaceuticals Inc., 235 East 42nd St., New York, NY 10017.
NDA 020214	ZEMURON (rocuronium bromide) Injectable; Injection 100 mg/10 milliliter (mL); 50 mg/5 mL; 10 mg/mL.	Organon USA Inc., 351 North Sunmeytown Pike, North Wales, PA 19454.
NDA 021040	PREFEST (estradiol; norgestimate) Tablet; Oral, 1 mg, 1 mg/0.09 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.
NDA 021621	CHILDREN'S ZYRTEC ALLERGY (cetirizine HCl) and CHILDREN'S ZYRTEC HIVES RELIEF (cetirizine HCl) Chewable Tablet; Oral, 5 mg; 10 mg.	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034.
NDA 050783	PERIOSTAT (doxycycline hyclate) Tablet; Oral, EQ 20 mg Base.	Galderma Laboratories, L.P., 14501 North Freeway, Fort Worth, TX 76177.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01859 Filed 1–30–15; 8:45 am]

BILLING CODE 4164–01–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.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than March 4, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Evaluation and Initial Assessment of the HRSA Teaching Health Centers Graduate Medical Education Program.

OMB No. 0906–xxxx—New.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to provide funding support for new and