Instructions: All submissions received must include the Docket No. FDA–2016–D–1692 for Elemental Impurities in Drug Products. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Kauffman, Center for Drug Evaluation and Research (HFD–920), Food and Drug Administration, 645 S. Newstead Ave., St. Louis, MO 63110, 314–539–2168; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Elemental Impurities in Drug Products.'' This draft guidance provides recommendations regarding the control of elemental impurities of human drug products marketed in the United States consistent with implementation of ICH Q3D. The draft guidance will also assist manufacturers of compendial drug products in responding to the issuance of the USP requirement for the control of elemental impurities.

USP introduced new limits and analytical procedures for elemental impurities in General Chapters Elemental Impurities—Limits and Elemental Impurities—Procedures. Their primary goals are to (1) set limits for acceptable levels of elemental impurities in finished drug products, and (2) update the methodology used to test for elemental impurities in drug products to include modern analytical procedures. ICH Q3D contains recommendations for manufacturers of human drugs and biologics on applying a risk-based approach to control elemental impurities and permitted daily exposure. USP worked closely with ICH to align its new General Chapters with ICH Q3D.

Because elemental impurities pose toxicological concerns and do not provide any therapeutic benefit to the patient, their levels in drug products should be controlled within acceptable limits. In general, FDA recommends that the manufacturer of any U.S. marketed drug product follow ICH Q3D recommendations to establish appropriate procedures for identifying and controlling elemental impurities in the drug product based on risk assessment and product-specific considerations, unless the drug product must comply with USP–NF requirements. This draft guidance outlines approaches for implementation of USP, and ICH Q3D in new and existing products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on elemental impurities in drug products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 for submitting NDAs and ANDAs, including supplemental applications and annual reports, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 211 and part 212 (CGMPs) have been approved under OMB control numbers 0910–0139 and 0910–0667.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: June 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15704 Filed 6–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1662]

Vulvovaginal Candidiasis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Vulvovaginal Candidiasis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of uncomplicated vulvovaginal candidiasis (VVC).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1662 for ''Vulvovaginal Candidiasis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Shrimant Mishra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6382, Silver Spring, MD 20993–0002, 301–796–1400.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Vulvovaginal Candidiasis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of uncomplicated VVC.

This guidance helps define enrollment criteria for VVC trials, and recommends that such trials be superiority trials against placebo or active control. The recommended efficacy endpoint is resolution of clinical signs and symptoms. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of VVC.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. In 1998, FDA published a draft guidance entitled ''Vulvovaginal Candidiasis: Developing Antimicrobial Drugs for Treatment'' (the 1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 2013 **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn because new information, scientific developments, and emerging technologies required a revision. FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15661 Filed 6–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of May 13, 2016, available on the Health Resources and Services Administration (HRSA) Web site at *http://www.hrsa.gov/shortage/.* HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

FOR FURTHER INFORMATION CONTACT: Requests for further information on the HPSA designations listed on the HRSA Web site below should be submitted to Kae Brickerd, Ph.D., Director, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, Mail Stop 11SWH03, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594–5168 or *KBrickerd@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. HPSAs are to be reviewed at least annually and revised as necessary. HRSA's BHW has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary care, mental, or dental health services in or to these HPSAs. NHSC health professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by BHW. Many other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare & Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists

Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989 (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHW. The majority of the requests come from the Primary Care Offices (PCO) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, interested parties, including the Governor, the State Primary Care Association and state professional associations are notified of each request submitted for their comments and recommendations.

Recommendations for possible additions, continuations, revisions, or withdrawals from a HPSA list are reviewed by BHW, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date on the notification letter from BHW. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHW in support of its continued or revised designation. If no new data are submitted, or if BHW review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the **Federal Register**. In addition, lists of HPSAs are updated daily on the HRSA Web site, *http://www.hrsa.gov/shortage/,* so that interested parties can access the most accurate and timely information.

Publication and Format of Lists

Due to the large volume of designations, a printed version of the list is no longer distributed. This notice serves to inform the public of the availability of the complete listings of designated HPSAs on the HRSA Web site. The three lists (primary medical care, mental health, and dental) of designated HPSAs are available at a link on the HRSA Web site at *http://www.hrsa.gov/shortage/* and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 13, 2016. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on July 1, 2015 (**Federal Register**/Vol. 80,