Summary: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of June 21, 2017 (82 FR 28322). The document announced the withdrawal of approval of 121 new drug applications (NDAs) and 161 abbreviated new drug applications from multiple applicants, withdrawn as of July 21, 2017. The document indicated that FDA was withdrawing approval of NDA 204508, Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%, after receiving a request from the NDA holder, Baxter Healthcare Corp. (Baxter), 32650 N Wilson Rd., Round Lake, IL 60073. Before the approval of NDA 204508 was withdrawn, Baxter informed FDA that it did not want the approval of this NDA withdrawn. Because Baxter timely requested that approval of this NDA not be withdrawn, the approval of NDA 204508 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In the Federal Register of Wednesday, June 21, 2017, appearing on page 28322 in FR Doc. 2017–12908, the following correction is made:

On page 28329, in table 1, the entry for NDA 204508 is removed.


Leslie Kux,
Associate Commissioner for Policy.

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### ANNUAL BURDEN ESTIMATES

<table>
<thead>
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<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<td>4</td>
<td>5</td>
<td>18,000</td>
</tr>
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</table>

**Estimated Total Annual Burden Hours:**

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

**OMB Comment**

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_submission@omb.eop.gov. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargsis, Reports Clearance Officer.

[FR Doc. 2018–03925 Filed 2–26–18; 8:45 am]

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**

[Docket No. FDA–2017–N–3203]

Wyeth Pharmaceuticals Inc. et al.; Withdrawal of Approval of 121 New Drug Applications and 161 Abbreviated New Drug Applications; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of June 21, 2017 (82 FR 28322). The document announced the withdrawal of approval of 121 new drug applications (NDAs) and 161 abbreviated new drug applications from multiple applicants, withdrawn as of July 21, 2017. The document indicated that FDA was withdrawing approval of NDA 204508, Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%, after receiving a request from the NDA holder, Baxter Healthcare Corp. (Baxter), 32650 N Wilson Rd., Round Lake, IL 60073. Before the approval of NDA 204508 was withdrawn, Baxter informed FDA that it did not want the approval of this NDA withdrawn. Because Baxter timely requested that approval of this NDA not be withdrawn, the approval of NDA 204508 is still in effect.

**FOR FURTHER INFORMATION CONTACT:** Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

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Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2018–03925 Filed 2–26–18; 8:45 am]

BILLING CODE 4164–01–P

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**

[Docket No. FDA–2018–N–0663]

Tissue Agnostic Therapies in Oncology: Regulatory Considerations for Orphan Drug Designation; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “Tissue Agnostic Therapies in Oncology: Regulatory Considerations for Orphan Drug Designation.” The purpose of the public workshop is to discuss factors FDA should consider when evaluating drugs for orphan designation that treat a tissue agnostic disease or condition in oncology, and additional factors related to orphan exclusivity FDA should consider when approving a product with a tissue agnostic indication.

**DATES:** The public workshop will be held on May 9, 2018, from 9 a.m. to 5 p.m. The public workshop may be extended or may end early depending on the level of public participation. Submit either electronic or written comments on this public workshop by June 8, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

**ADDRESSES:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of June 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**Electronic Submissions**

Submit electronic comments in the following way:

* Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–0663 for “Tissue Agnostic Therapies in Oncology: Regulatory Considerations for orphan Drug Designation; Public Workshop; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the website by April 25, 2018:

https://www.fda.gov/NewsEvents/Meetings/ConferencesWorkshops/ucm592778.htm.

III. Participating in the Public Workshop
Registration: To register for the public workshop, please visit the following website by April 25, 2018: https://
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Service Administration

Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Applicable as of December 29, 2017, HRSA updated the HRSA-supported Women’s Preventive Services Guidelines for purposes of health insurance coverage for preventive services that address health needs specific to women based on clinical recommendations from the Women’s Preventive Services Initiative. This 2017 update adds two additional services—Screening for Diabetes Mellitus after Pregnancy and Screening for Urinary Incontinence—to the nine preventive services included in the 2016 update to the HRSA-supported Women’s Preventive Services Guidelines. The nine services included in the 2016 update are as follows: Breast Cancer Screening for Average Risk Women, Breastfeeding Services and Supplies, Screening for Cervical Cancer, Contraception, Screening for Gestational Diabetes Mellitus, Screening for Human Immunodeficiency Virus Infection, Screening for Interpersonal and Domestic Violence, Counseling for Sexually Transmitted Infections, and Well-Woman Preventive Visits. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see https://www.hrsa.gov/womens-guidelines/index.html for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly C. Sherman, Maternal and Child Health Bureau, HRSA at phone: (301) 443–0543; email: wellwoman@hrsa.gov.

SUPPLEMENTARY INFORMATION: The complete set of updated 2017 HRSA-supported Women’s Preventive Services Guidelines includes those that were accepted by the Acting HRSA Administrator on December 20, 2016, as well as two new services, Screening for Diabetes Mellitus After Pregnancy and Screening for Urinary Incontinence. For a complete listing and detailed information about the December 20, 2016, updates, please see https://www.federalregister.gov/documents/2016/12/27/2016-31129/updating-the-hrsa-supported-womens-preventive-services-guidelines. In addition, the December 20, 2016, updates, including information related to coverage of contraceptive services and exemption for objecting organizations from requirements related to the provision of contraceptive services, can be found at https://www.hrsa.gov/womens-guidelines-2016/index.html.

Information regarding the two new services that were accepted by the HRSA Administrator on December 29, 2017, is set out below:

1. Screening for Diabetes Mellitus After Pregnancy

The Women’s Preventive Services Initiative recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum.

Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (e.g., oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first six months postpartum regardless of the result (see Implementation Considerations below).

2. Screening for Urinary Incontinence

The Women’s Preventive Services Initiative recommends screening women for urinary incontinence annually. Screening should ideally assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. The Women’s Preventive Services Initiative recommends referring women for further evaluation and treatment if indicated.

HRSA-Supported Women’s Preventive Services Guidelines

The HRSA-supported Women’s Preventive Services Guidelines were originally established in 2011 based on recommendations from an HHS commissioned study by the Institute of Medicine, now known as the National...