

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 086034	Isosorbide Dinitrate Tablets USP, 5 mg .....	Do.
ANDA 086188	Gerimal (ergoloid mesylates) Sublingual Tablets, 1 mg .....	Do.
ANDA 086385	Nandrolone Decanoate Injection, 50 mg/mL .....	Do.
ANDA 086562	Wigraine (ergotamine tartrate and caffeine) Tablets USP, 1 mg/100 mg.	Organon USA, Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
ANDA 086742	Choledyl SA (oxtriphylline) Extended-Release Tablets, 600 mg	Warner Chilcott Co., LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 086863	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL .....	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087233	Ergoloid Mesylates Sublingual Tablets USP, 0.5 mg .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087244	Ergoloid Mesylates Tablets USP, 1 mg .....	Do.
ANDA 087318.	Tolbutamide Tablets USP, 500 mg .....	Do.
ANDA 087727	Aminophylline Oral Solution USP, 105 mg/5 mL (Dye Free) .....	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088128	Nandrolone Decanoate Injection, 200 mg/mL .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088337	Ergostat (ergotamine tartrate) Sublingual Tablets USP, 2 mg ...	Do.
ANDA 088477	Thioridazine HCl Tablets USP, 15 mg .....	Do.
ANDA 088561	Thioridazine HCl Tablets USP, 10 mg .....	Do.
ANDA 088564	Thioridazine HCl Tablets USP, 100 mg .....	Do.
ANDA 088724	Methyclothiazide Tablets USP, 5 mg .....	Do.
ANDA 088734	Meclizine HCl Tablets, 25 mg .....	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088769	Mepivacaine HCl Injection USP, 1% .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088770	Mepivacaine HCl Injection USP, 2% .....	Do.
ANDA 088872	Thioridazine HCl Tablets USP, 200 mg .....	Do.
ANDA 089026	Procainamide HCl Extended-Release Tablets USP, 250 mg ....	Do.
ANDA 089027	Procainamide HCl Extended-Release Tablets USP, 500 mg ....	Do.
ANDA 089530	Prochlorperazine Edisylate Injection USP, EQ 5 mg base/mL ..	Do.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 1, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see **DATES**) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28254 Filed 12-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-5715]

#### **Watson Laboratories, Inc., and Barr Laboratories, Inc., Subsidiaries of Teva Pharmaceuticals USA, Inc.; Withdrawal of Approval of 54 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 October 24, 2017. The document announced the withdrawal of approval of 54 abbreviated new drug applications (ANDAs) from two applicants, effective November 24, 2017. The notice inadvertently announced the withdrawal of approval for ANDA 087296 for Chlorthalidone Tablets USP, 25 milligrams, held by Watson Laboratories, Inc., a subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044. FDA confirms that the approval of ANDA 087296 is still in effect.

#### **FOR FURTHER INFORMATION CONTACT:**

Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2017-23046, appearing on page 49214 in the **Federal Register** of Tuesday, October 24, 2017, the following correction is made:

1. On page 49215, in table 1, the entry for ANDA 087296 is removed.

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28253 Filed 12-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-1846]

#### **Labeling for Combined Hormonal Contraceptives; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Labeling for Combined Hormonal Contraceptives.” This draft guidance provides recommendations on information that should be included in the prescribing information for combined hormonal contraceptives (CHCs), which contain estrogen and progestin. CHC products include combined oral contraceptives (COCs), as well as non-oral products such as transdermal systems and vaginal rings. Many of the labeling recommendations in this draft guidance represent class labeling that should be included in all CHC prescribing information. The draft guidance reflects many of the modifications to prescribing information mandated by the physician labeling rule (PLR) and the pregnancy and lactation labeling rule (PLLR). General advice is provided where modifications to the prescribing information for specific products are needed.

**DATES:** Submit either electronic or written comments on the draft guidance by March 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *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-2017-D-1846 for “Labeling for Combined Hormonal Contraceptives; Draft Guidance for Industry.” Received comments 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 and the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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:** Jennifer Dao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5333, Silver Spring, MD 20993-0002, 301-796-8189.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Labeling for Combined Hormonal Contraceptives.” This draft guidance provides recommendations on information that should be included in the prescribing information for CHCs, which contain estrogen and a progestin. Such products include COCs, as well as non-oral products such as transdermal systems and vaginal rings. Many of the labeling recommendations in this draft guidance represent class labeling that should be included in all CHC prescribing information. The draft guidance reflects many of the modifications to prescribing information mandated by the PLR<sup>1</sup> and the PLLR.<sup>2</sup>

<sup>1</sup> See the final rule “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” (71 FR 3922, January 24, 2006) (21 CFR 201.56(d)(1) and 201.57(c)(9)(i) through (iii)); see also the guidance for industry entitled “Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements” available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075082.pdf>.

<sup>2</sup> See the final rule “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling” (79 FR 72064, December 4, 2014) (21 CFR 201.56(d) and 201.57); see also the draft guidance for industry entitled “Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format” available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425398.pdf>. When final, this guidance will represent FDA’s current thinking on this topic.

General advice is provided where modifications of the prescribing information for specific products are needed.

FDA previously issued draft guidance on the prescribing information for COCs in March 2004 and invited public comment. That draft guidance was withdrawn in July 2015. However, the development of the current draft guidance took into consideration public comments submitted to the 2004 draft guidance that were science-based and consistent with current PLR and PLLR labeling regulations. This draft guidance has been broadened to incorporate the more general class of CHCs.

FDA invites comments on the content of this draft guidance. In particular, FDA seeks comments on the proposed language under section 7.1 of labeling that identifies a drug interaction with all metabolic enzyme inducers. A variety of metabolic enzyme inducers have been reported to decrease the plasma concentration of the estrogen and/or progestin components of CHCs. FDA seeks comments and data regarding specific enzyme inducers or classes of inducers (e.g., cytochrome p450 3A strong inducers) that interact with CHCs; in particular, comments are requested on whether the CHC labeling should include specific inducers or classes of inducers, or if it should remain broad and essentially cover all possible cytochrome p (CYP) enzyme inducers of any pathway and potency.

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 labeling for CHCs. 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. This guidance is not subject to Executive Order 12866.

## II. 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 201.56 and 201.57 (“Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products”) are approved under OMB control number 0910–0572. The collections of information from the final rule entitled “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements

for Pregnancy and Lactation Labeling” are approved under OMB control number 0910–0624.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov/>.

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–28252 Filed 12–29–17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–2347]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with export certificate applications for FDA-regulated food and cosmetic products.

**DATES:** Submit either electronic or written comments on the collection of information by March 5, 2018.

**ADDRESSES:** 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 March 5, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 5, 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–2014–N–2347 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process.” 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