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**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 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.

**FOR FURTHER INFORMATION CONTACT:** Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the

FDA’s website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The committees will be asked to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Charleston Laboratories, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term management of acute pain severe enough to require an opioid analgesic while preventing and reducing opioid-induced nausea and vomiting. The committees will also be asked to discuss the abuse potential of this non-abuse-deterrent product and whether it should be approved.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before January 31, 2018. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 23, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons

regarding their request to speak by January 24, 2018.

Persons attending FDA’s advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-28250 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-6852]

#### **Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc. et al.; Withdrawal of Approval of 111 Abbreviated New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 111 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of February 1, 2018.

**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,  
Trang.Tran@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in table 1 have informed FDA that these

drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their

opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

| Application No. | Drug   | Applicant   |
|-----------------|--|---|
| ANDA 040008     | Heparin Sodium Injection USP, 1000 units/milliliter (mL) .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044. |
| ANDA 040137     | Chlorzoxazone Tablets USP, 500 milligrams (mg) .....   | Do.   |
| ANDA 040410     | Methylphenidate Hydrochloride (HCl) Extended-Release Tablets USP, 20 mg.   | Do.   |
| ANDA 040456     | Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets, 1.25 mg/1.25 mg/1.25 mg/1.25 mg, 2.5 mg/2.5 mg/2.5 mg/2.5 mg, 5 mg/5 mg/5 mg/5 mg, and 7.5 mg/7.5 mg/7.5 mg/7.5 mg. | Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.    |
| ANDA 040666     | A-Hydrocort (hydrocortisone sodium succinate) for Injection USP, Equivalent to (EQ) 100 mg base/vial.  | Hospira, Inc., a Pfizer Company, 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.                      |
| ANDA 062520     | Kanamycin Sulfate Injection, EQ 1 gram (g) base/3 mL .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 062693     | Cephadrine for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL.   | Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.  |
| ANDA 062844     | Nafcillin for Injection USP, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 1.5 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial.  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 062856     | Oxacillin for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial.   | Do.   |
| ANDA 062984     | Oxacillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).  | Do.   |
| ANDA 062991     | Penicillin G Potassium for Injection USP, 1 million units/vial, 5 million units/vial, 10 million units/vial, and 20 million units/vial.  | Do.   |
| ANDA 063008     | Nafcillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).  | Do.   |
| ANDA 063014     | Penicillin G Sodium for Injection USP, 5 million units/vial .....  | Do.   |
| ANDA 063106     | Gentamicin Injection USP, EQ 40 mg base/mL .....   | Teva Pharmaceuticals USA, Inc.  |
| ANDA 064035     | Cefuroxime for Injection USP, EQ 750 mg base/vial and EQ 1.5 g base/vial.  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 065280     | Cefazolin for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.   | Cephazone Pharma, LLC, 250 E. Bonita Ave., Pomona, CA 91767.  |
| ANDA 065294     | Ceftriaxone for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial.   | Do.   |
| ANDA 065295     | Cefazolin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).  | Do.   |
| ANDA 065296     | Cefazolin for Injection USP, EQ 20 g base/vial (Pharmacy Bulk Package).  | Do.   |
| ANDA 070301     | Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg.  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 070305     | Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg.  | Do.   |
| ANDA 070468     | Verapamil HCl Tablets USP, 120 mg .....  | Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.  |
| ANDA 070549     | Propranolol HCl Tablets USP, 20 mg .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 070703     | Methyldopa Tablets USP, 250 mg .....   | Do.   |
| ANDA 070714     | Haloperidol Injection USP, EQ 5 mg base/mL .....   | Do.   |
| ANDA 070851     | Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg.  | Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.  |
| ANDA 070852     | Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg.  | Do.   |
| ANDA 070855     | Verapamil HCl Tablets USP, 80 mg .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                                     |
| ANDA 070958     | Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg.  | Do.   |
| ANDA 070959     | Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg.  | Do.   |
| ANDA 070960     | Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/50 mg.  | Do.   |

TABLE 1—Continued

| Application No. | Drug  | Applicant   |
|-----------------|---|---|
| ANDA 071069     | Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/30 mg.   | Do.   |
| ANDA 071110     | Lorazepam Tablets USP, 2 mg .....   | Do.   |
| ANDA 071117     | Lorazepam Tablets USP, 0.5 mg .....   | Do.   |
| ANDA 071118     | Lorazepam Tablets USP, 1 mg .....   | Do.   |
| ANDA 071485     | Doxepin HCl Capsules USP, EQ 10 mg base .....   | Do.   |
| ANDA 071486     | Doxepin HCl Capsules USP, EQ 25 mg base .....   | Do.   |
| ANDA 071666     | Ibuprofen Tablets, 400 mg .....   | Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044. |
| ANDA 071792     | Propranolol HCl Tablets USP, 90 mg .....  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                       |
| ANDA 071883     | Betamethasone Valerate Lotion USP, EQ 0.1% base .....   | Teva Pharmaceuticals USA, Inc.  |
| ANDA 071919     | Nalidixic Acid Tablets USP, 1 g .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                       |
| ANDA 071936     | Nalidixic Acid Tablets USP, 250 mg .....  | Do.   |
| ANDA 072061     | Nalidixic Acid Tablets USP, 500 mg .....  | Do.   |
| ANDA 072164     | Maprotiline HCl Tablets USP, 75 mg .....  | Do.   |
| ANDA 072795     | Metaproterenol Sulfate Tablets USP, 20 mg .....   | Do.   |
| ANDA 072824     | Baclofen Tablets USP, 10 mg .....   | Do.   |
| ANDA 073373     | Morphine Sulfate Injection USP, 1 mg/2 mL (Ampule) .....  | Do.   |
| ANDA 073374     | Morphine Sulfate Injection USP, 10 mg/10 mL (Ampule) .....  | Do.   |
| ANDA 073375     | Morphine Sulfate Injection USP, 5 mg/10 mL (Vial) .....   | Do.   |
| ANDA 073376     | Morphine Sulfate Injection USP, 10 mg/10 mL (Vial) .....  | Do.   |
| ANDA 073443     | Meperidine HCl Injection USP, 10 mg/mL (Preservative Free) .....                                      | Do.   |
| ANDA 073444     | Meperidine HCl Injection USP, 50 mg/mL .....  | Do.   |
| ANDA 073529     | Doxapram HCl Injection USP, 20 mg/mL .....  | Do.   |
| ANDA 074032     | Metoprolol Tartrate Injection USP, 1 mg/mL .....  | Do.   |
| ANDA 074195     | Naproxen Sodium Tablets USP, EQ 250 mg base and EQ 500 mg base.                                       | Do.   |
| ANDA 074276     | Lorazepam Injection USP, 2 mg/mL and 4 mg/mL .....  | Do.   |
| ANDA 074279     | Dobutamine Injection USP, EQ 12.5 mg base/mL .....  | Do.   |
| ANDA 074393     | Isoflurane USP, 99.9% .....   | Do.   |
| ANDA 074457     | Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg .....  | Do.   |
| ANDA 074598     | Hydromorphone HCl Injection USP, 10 mg/mL .....   | Hospira, Inc.   |
| ANDA 074864     | Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base.  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                       |
| ANDA 074906     | Acyclovir Capsules USP, 200 mg .....  | Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.                          |
| ANDA 075253     | Ticlopidine HCl Tablets, 250 mg .....   | Do.   |
| ANDA 075650     | Famotidine Tablets USP, 20 mg and 40 mg .....   | Do.   |
| ANDA 075672     | Bisoprolol Fumarate and Hydrochlorothiazide Tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg. | Do.   |
| ANDA 075843     | Oxaprozin Tablets, 600 mg .....   | Do.   |
| ANDA 075901     | Fluvoxamine Maleate Tablets, 25 mg, 50 mg, and 100 mg .....   | Do.   |
| ANDA 075960     | Tramadol HCl Tablets, 50 mg .....   | Do.   |
| ANDA 076689     | Mirtazapine Orally Disintegrating Tablets USP, 15 mg, 30 mg, and 45 mg.                               | Do.   |
| ANDA 077174     | Foscarnet Sodium Injection, 2.4 g/100 mL .....  | Hospira, Inc.   |
| ANDA 077963     | Granisetron HCl Injection, EQ 1 mg base/mL .....  | Teva Pharmaceuticals USA, Inc.  |
| ANDA 080615     | Dimenhydrinate Injection, 50 mg/mL .....  | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                       |
| ANDA 080713     | Tripelennamine HCl Tablets USP, 50 mg .....   | Do.   |
| ANDA 081150     | Hydroxyzine HCl Tablets USP, 25 mg .....  | Do.   |
| ANDA 081151     | Hydroxyzine HCl Tablets USP, 50 mg .....  | Do.   |
| ANDA 083287     | Procainamide HCl Capsules USP, 250 mg .....   | Do.   |
| ANDA 084280     | Procainamide HCl Capsules USP, 500 mg .....   | Do.   |
| ANDA 084403     | Procainamide HCl Capsules USP, 375 mg .....   | Do.   |
| ANDA 084467     | Reserpine and Hydrochlorothiazide Tablets USP, 0.125 mg/50 mg.  | Do.   |
| ANDA 085083     | Diphenhydramine HCl Capsules USP, 50 mg .....   | Do.   |
| ANDA 085140     | Quinidine Sulfate Tablets USP, 200 mg .....   | Do.   |
| ANDA 085173     | Chlorothiazide Tablets USP, 250 mg .....  | Do.   |
| ANDA 085180     | Methocarbamol Tablets USP, 500 mg .....   | Do.   |
| ANDA 085192     | Methocarbamol Tablets USP, 750 mg .....   | Do.   |
| ANDA 085597     | Methylprednisolone Acetate Injectable Suspension USP, 20 mg/mL.                                       | Do.   |
| ANDA 086013     | Statobex (phendimetrazine tartrate) Tablets USP, 35 mg .....  | Teva Pharmaceuticals USA, Inc.  |
| ANDA 086029     | Testosterone Cypionate Injection USP, 100 mg/mL .....   | Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.                       |
| ANDA 086031     | Isosorbide Dinitrate Sublingual Tablets USP, 5 mg .....   | Do.   |

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.