

the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 known generally as the "Orange Book." Under FDA regulations, drugs are 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AZO GANTANOL is the subject of NDA 013294, held by Roche and approved on April 8, 1965. AZO GANTRISIN is the subject of NDA 019358, held by Roche and initially approved on August 31, 1990. Under the Drug Efficacy Study Implementation (DESI), FDA concluded that a fixed combination drug product containing 500 mg of sulfamethoxazole and 100 mg of phenazopyridine HCl, and certain other sulfonamide/phenazopyridine combinations, are effective for indications described in a **Federal Register** notice published on July 29, 1983 (DESI 12056, 48 FR 34516). Consistent with that determination, both AZO GANTANOL and AZO GANTRISIN are indicated for the initial treatment of uncomplicated urinary tract infections caused by susceptible strains of *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Proteus mirabilis*, *Proteus vulgaris*, and *Staphylococcus aureus* when relief of symptoms of pain, burning, or urgency is needed during the first 2 days of therapy.

In a letter dated May 29, 1998, Roche requested that FDA withdraw approval

of NDA 013294 for AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg. In the **Federal Register** of September 25, 1998 (63 FR 51359), FDA announced that it was withdrawing approval of NDA 013294 effective September 25, 1998.

In a letter dated March 23, 1998, Roche requested that FDA withdraw approval of NDA 019358 for AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg. In the **Federal Register** of May 12, 1998 (63 FR 26191), FDA announced that it was withdrawing approval of NDA 019358 effective June 11, 1998.

Vintage Pharmaceuticals, LLC, submitted a citizen petition dated December 1, 2006 (Docket No. FDA-2006-P-0136), under 21 CFR 10.30, requesting that FDA determine whether AZO GANTANOL and AZO GANTRISIN were withdrawn from sale for reasons of safety or effectiveness. JRRapoza Associates, Inc., submitted a citizen petition dated January 17, 2007 (Docket No. FDA-2007-P-0353), under 21 CFR 10.30, also requesting that FDA determine whether AZO GANTANOL and AZO GANTRISIN were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. We have also independently evaluated relevant literature and have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other things, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to either AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, or AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, may be approved by the Agency if all

other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that the labeling for either drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0725]

#### Draft Guidance for Industry on Abbreviated New Drug Application Submissions; Content and Format of Abbreviated New Drug Applications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA Submissions—Content and Format of Abbreviated New Drug Applications." The guidance document is intended to assist applicants in preparing complete and high-quality original abbreviated new drug applications (ANDAs) for submission to FDA under the Federal Food, Drug, and Cosmetic Act. The guidance summarizes the statutory and regulatory requirements for ANDAs, references existing guidance documents, and incorporates additional recommendations on the content and format of ANDA submissions. This guidance describes the Common Technical Document format for human pharmaceutical product applications and specifies the information to be submitted in each section of the application.

**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 August 11, 2014.

**ADDRESSES:** 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, 10903 New

Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, email: [elizabeth.giaquinto@fda.hhs.gov](mailto:elizabeth.giaquinto@fda.hhs.gov), or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance for industry entitled “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” On July 9, 2012, the Generic Drug User Fee Amendments (GDUFA) was signed into law by the President to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter. Among these obligations is FDA’s commitment to performance metrics for the review of original ANDAs. For example, FDA has committed to review and act on 90 percent of original ANDA submissions within 10 months from the date of submission in Year 5 of the program, which begins on October 1, 2016.

In an effort to increase the number of original ANDAs that the Agency can receive upon initial submission and to decrease the number of review cycles required to approve an application for marketing, FDA prepared this guidance on improving the quality of original ANDA submissions. FDA is committed to providing comprehensive assistance in the early stages of the application process to ensure that an original ANDA

contains all information necessary for FDA to complete its review in one review cycle.

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 Agency’s current thinking on “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 314.94 have been approved under 0910-0001. The collection of information in Form FDA 356h has been approved under 0910-0338. The collection of information for Form FDA 3674 has been approved under 0910-0616. The collection of information for Form FDA 3794 has been approved under 0910-0727. The collection of information for Form FDA 3454 has been approved under 0910-0393. The collection of information for Form FDA 3455 has been approved under 0910-0396. The collection information for 21 CFR part 11, Electronic Records, has been approved under 0910-0303.

##### **III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

##### **IV. Electronic Access**

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

*GuidanceComplianceRegulatoryInformation/default.htm*, or <http://www.regulations.gov>.

Dated: June 5, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2013-N-1504]**

#### **Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice entitled “Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan” that appeared in the **Federal Register** of May 29, 2014 (79 FR 30853). The document announced Booz Allen Hamilton’s final comprehensive findings and recommendations submitted as part of their independent assessment of the process for the review of medical device submissions as well as FDA’s first implementation plan based on Booz Allen Hamilton’s high priority recommendations issued December 11, 2013. The notice was issued earlier than intended. The documents will be available on June 11, 2014, as required by the Medical Device User Fee Amendments of 2012 (MDUFA) III Performance Goals and Procedures Commitment Letter.

**FOR FURTHER INFORMATION CONTACT:** Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3291, Silver Spring, MD 20993-0002, 301-796-9384, [Amber.Sligar@fda.hhs.gov](mailto:Amber.Sligar@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Thursday, May 29, 2014, in FR Doc. 2014-12403, on pages 30853-30854, the following correction is made:

The notice implied that Booz Allen Hamilton’s final comprehensive findings and recommendations and FDA’s first implementation plan are available as of May 29, 2014. In fact, the