



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

Christopher J. Nascone
Regulatory Affairs
Vintage Pharmaceuticals, LLC
150 Vintage Dr.
Huntsville, AL 35811

JUN 12 2014

Re: Docket No. FDA-2006-P-0136¹

Dear Mr. Nascone:

This letter responds to your citizen petition, received on December 4, 2006, requesting that the Food and Drug Administration (FDA) determine whether the following drug products were withdrawn from sale for reasons of safety or effectiveness: (1) AZO GANTANOL (phenazopyridine hydrochloride (HCl) and sulfamethoxazole) Tablet, 100 milligrams (mg)/500 mg and (2) AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg.

FDA has reviewed its records and determined that AZO GANTANOL and AZO GANTRISIN were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain 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 *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of a *Federal Register* notice that announces FDA's determination.

If you require any further information, please feel free to call me at 301-796-3601.

Sincerely,

David Joy
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

¹ This citizen petition was originally assigned docket number 2006P-0469. The number changed to FDA-2006-P-0136 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

for Drug Establishment Registration.” Sections 701 and 702 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This draft guidance specifies the UFI system as follows. At this time, FDA’s preferred UFI for a drug establishment is the Data Universal Numbering System D–U–N–S (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting the Web site for Dun and Bradstreet. As explained in the guidance, however, if a company wants to use an alternative UFI for its drug establishment, it may contact FDA via email at edrls@fda.hhs.gov.

OMB has previously approved existing information collections associated with the electronic submission of initial and annual registration of domestic and foreign drug establishments, as described in part 207 (21 CFR part 207) and the guidance document “Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing” (the 2009 Guidance) (available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072339.pdf>), under OMB control number 0910–0045. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) required that drug establishment registration and drug listing information must be submitted electronically unless a waiver is granted. As part of its recommendations to facilitate electronic submission of drug establishment registration information, as required by statute, the 2009 guidance explained that FDA is adopting the use of extensible markup language files in a standard structured product labeling format for the electronic submission of drug establishment registration and drug listing information. The 2009 guidance also explained that the automated submission process functions most efficiently and effectively when the information is provided in a standardized format with defined code sets and codes. In addition, the 2009 guidance requested, among other things, the electronic submission of a site-

specific DUNS number for each entity as part of the registration information submitted electronically. In FDA’s experience, all firms currently registered with FDA under section 510 of the FD&C Act and part 207 have submitted their DUNS number as requested in the 2009 guidance.

The guidance modifies the currently approved information collections associated with drug establishment registration, consistent with subsequent statutory enactment. In July 2012, Congress enacted FDASIA, sections 701 and 702 of which direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI. Because drug firms generally possess, and for those already registered, have previously provided, a DUNS number for each facility, FDA expects that consistent with the proposed UFI system, they will submit DUNS numbers as the UFIs for drug establishments. Although the change in statutory authority described in this document will alter the legal basis for submission of the DUNS number, it is not expected to have any other impact on the previously approved collection of information. FDA expects that the DUNS number will continue to be submitted by the same respondents, with the same frequency, as part of the same electronic registration submission previously approved under the PRA, and the Agency will continue to use the information for the same purposes, in furtherance of its mission to protect the public health.

While FDA anticipates that firms will submit DUNS as UFI, the guidance also suggests that firms who want to submit an alternative identifier contact FDA. FDA estimates that no more than one respondent per year will invoke this option. FDA estimates that it would require on average 1 hour for a company to contact FDA and identify its proposed alternative UFI.

In the **Federal Register** of September 6, 2013 (78 FR 54899), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments that did not pertain to the information collection. Upon review of these comments FDA does not plan to revise the information collection.

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13788 Filed 6–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–P–0136 (Formerly Docket No. 2006P–0496) and Docket No. FDA–2007–P–0353 (Formerly Docket No. 2007P–0034)]

Determination That AZO GANTANOL (Phenazopyridine Hydrochloride, Sulfamethoxazole) Tablet, 100 Milligrams/500 Milligrams, and AZO GANTRISIN (Phenazopyridine Hydrochloride, Sulfisoxazole) Tablet, 50 Milligrams/500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that AZO GANTANOL (phenazopyridine hydrochloride (HCl) and sulfamethoxazole) Tablet, 100 milligrams (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. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for phenazopyridine HCl and sulfamethoxazole tablet, 100 mg/500 mg, and phenazopyridine HCl and sulfisoxazole tablet, 50 mg/500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of

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.

[FR Doc. 2014-13757 Filed 6-11-14; 8:45 am]

BILLING CODE 4164-01-P

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