

### B. Length of Support

This Cooperative Agreement established with NACCHO has the possibility of 4 additional years of support for up to \$400,000 per year, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

### III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.fda.gov/Food/NewsEvents/default.htm>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at <http://grants.nih.gov/grants/forms.htm>, for all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>.

After you have followed these steps, submit paper applications to the following. Please note that the application should not be submitted through Grants.gov or eRA Commons: Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS) (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175, [gladys.bohler@fda.hhs.gov](mailto:gladys.bohler@fda.hhs.gov).

Dated: June 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-14059 Filed 6-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0008]

#### Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) addressing the Agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The guidance describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. The guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The guidance also addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:** Kimberly K. Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 301-796-3601.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." In the **Federal Register** of January 21, 2009 (74 FR 3611), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. As described in the January 21, 2009, **Federal Register** notice, the guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of FDAAA (Pub. L. 110-85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA or a 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Agency has carefully reviewed and considered the comments it received in response to the draft guidance in developing this final version of the guidance. The Agency has added information in sections III.C and III.D of the guidance to further explain how FDA will apply the certification

and verification requirements of section 505(q) and has also made revisions to clarify aspects of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on citizen petitions and petitions for stay of action that are subject to section 505(q) of the FD&C Act. 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 guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control number 0910-0679. This guidance also refers to previously approved collections of information found in FDA regulations and approved under OMB control number 0910-0183 (21 CFR 10.20, 10.30, and 10.35) and OMB control number 0910-0001 (21 CFR 314.54, 314.94, and 314.102).

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written

comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

**IV. Electronic Access**

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

Dated: June 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0411]

**Bristol-Myers Squibb Co. et al.;  
Withdrawal of Approval of 70 New  
Drug Applications and 97 Abbreviated  
New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 70 new drug applications (NDAs) and 97 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:** *Effective Date:* July 8, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Florine P. 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:** The holders of the applications listed in table 1 of this document 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
NDA 007289 .....	Trigesic and Trigesic with Codeine Tablets .....	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000.
NDA 008248 .....	Wyamine (mephentermine sulfate) Sulfate Injection .....	Baxter Healthcare Corp., 2 Esterbrook Lane, Cherry Hill, NJ 08003-4099.
NDA 008834 .....	Tronothane HCl (pramoxine hydrochloride (HCl)) .....	Abbott Laboratories, Dept. PA76/Bldg. AP30-1E, 200 Abbott Park Rd., Abbott Park, IL 60064-6157.
NDA 009182 .....	Gantrisin (sulfisoxazole acetyl) .....	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199.
NDA 011835 .....	Hydrodiuril (hydrochlorothiazide (HCTZ)) Tablets .....	Merck & Co., Inc., P.O. Box 1000, UG2C-50, North Wales, PA 19454.
NDA 011971 .....	Oretic (HCTZ) Tablets, 25 milligrams (mg) and 50 mg ..	Abbott Laboratories.
NDA 012302 .....	Choloxin (dextrothyroxine sodium) Tablets, 1 mg, 2 mg, 4 mg, and 6 mg.	Do.
NDA 013402 .....	Aldoril (methyldopa/HCTZ) Tablets .....	Merck & Co., Inc.
NDA 015539 .....	Serax (oxazepam) Capsules and Tablets .....	Alpharma U.S. Pharmaceuticals Division, c/o King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
NDA 016118 .....	Teslac (testolactone) Tablets .....	Bristol-Myers Squibb Co.
NDA 016402 .....	Alupent (metaproterenol sulfate) Inhalation Aerosol <sup>1</sup> .....	Boehringer Ingelheim, 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368.
NDA 016666 .....	Hippuran (hippuran I-131) Injection .....	Mallinckrodt Medical Inc., c/o Covidien, 675 McDonnell Blvd., Hazelwood, MO 63042.
NDA 016979 .....	Megace (megestrol acetate) Tablets, 20 mg and 40 mg	Bristol-Myers Squibb Co.
NDA 017015 .....	Pavulon (pancuronium bromide) Injection .....	Organon USA Inc., c/o Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033-0530.
NDA 017352 .....	Fastin (phentermine HCl) Capsules .....	GlaxoSmithKline, P.O. Box 13398, Five Moore Dr., Research Triangle Park, NC 27709-3398.