

conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (NAO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an NAO is voluntary and is not required for Medicare participation.

If an NAO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A NAO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the NAO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of NAOs are set forth at § 488.5.

## II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a NAO's requirements consider, among other factors, the applying NAO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Institute for Medical Quality (IMQ's) request for initial CMS-approval of its ASC accreditation program. This notice also solicits public comment on whether IMQ's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ASCs.

## III. Evaluation of a NAO's Accreditation Program

IMQ submitted all the necessary materials to enable us to make a determination concerning its request for initial CMS-approval of its ASC accreditation program. This application was determined to be complete on October 8, 2015. Under Section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of IMQ will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of IMQ's standards for ASCs as compared with Medicare's CfCs or ASCs.

- IMQ's survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- ++ The comparability of IMQ's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ IMQ's processes and procedures for monitoring an ASC found out of compliance with IMQ's program requirements. These monitoring procedures are used only when IMQ identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

- ++ IMQ's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ IMQ's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ The adequacy of IMQ's staff and other resources, and its financial viability.

- ++ IMQ's capacity to adequately fund required surveys.

- ++ IMQ's policies with respect to whether surveys are announced or

unannounced, to assure that surveys are unannounced.

- ++ IMQ's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: November 18, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-4399]

### Determination That OPHTHAINE (propraracaine hydrochloride) Solution and Other Drug Products 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 or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means

that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, [Stacy.Kane@fda.hhs.gov](mailto:Stacy.Kane@fda.hhs.gov).

**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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 generally known as the "Orange Book." Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 008883 .....	OPHTHAINE (proparacaine hydrochloride) Solution/Drops; Ophthalmic, 0.5%.	Apothecon, Inc.
NDA 009053 .....	PURINETHOL (mercaptapurine) Tablet; Oral, 50 milligrams (mg).	Teva Pharmaceuticals USA.
NDA 012427 .....	DIDREX (benzphetamine hydrochloride) Tablet; Oral, 50 mg	Pharmacia & Upjohn Co.
NDA 012583 .....	OPHTHETIC (proparacaine hydrochloride) Solution/Drops; Ophthalmic, 0.5%.	Allergan Pharmaceutical.
NDA 017716 .....	OVCON-35 (ethinyl estradiol; norethindrone) Tablet; Oral-28, 0.035 mg; 0.4 mg.	Warner Chilcott LLC.
NDA 018782 .....	NORDETTE-28 (ethinyl estradiol; levonorgestrel) Tablet; Oral-28, 0.03 mg; 0.15 mg.	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 021199 .....	QUIXIN (levofloxacin) Solution/Drops; Ophthalmic, 0.5% .....	Santen, Inc.
NDA 021595 .....	SANCTURA (trospium chloride) Tablet; Oral, 20 mg .....	Allergan, Inc.
NDA 021664 .....	BROMDAY (bromfenac sodium) Solution/Drops; Ophthalmic, EQ 0.09% acid.	Bausch & Lomb, Inc.
NDA 022103 .....	SANCTURA XR (trospium chloride) Extended-Release Capsule; Oral, 60 mg.	Allergan, Inc.
ANDA 060571 ....	MYCOSTATIN (nystatin) Ointment; Topical, 100,000 units/gram (g).	Delcor Asset Corp.
ANDA 060575 ....	MYCOSTATIN (nystatin) Cream; Topical, 100,000 units/g .....	Do.
ANDA 060578 ....	MYCOSTATIN (nystatin) Powder; Topical 100,000 units/g .....	Do.
ANDA 063116 ....	TOBRAMYCIN SULFATE (PHARMACY BULK) (tobramycin sulfate) Injectable; Injection, EQ 40 mg base/milliliter.	Hospira, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this

document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Drug Abuse;  
Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose