

5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1278.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), notice is given that a color additive petition (CAP 7C0283) has been filed by Nippon Oil Corp., c/o Beckloff Assoc., 7400 West 110th St., suite 300, Overland Park, KS 66210. The petition proposes to amend the color additive regulations in 21 CFR part 73 to provide for the safe use of *Paracoccus carotinifaciens* granules as a color additive in the feed of salmonid fish to enhance the color of their flesh.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 28, 2007.

**Laura M. Tarantino,**  
Director, Office of Food Additive Safety,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. E7-13161 Filed 7-6-07; 8:45 am]  
BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0221]

#### Otsuka Pharmaceutical Co., Ltd.; Withdrawal of Approval of a New Drug Application; 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 June 14, 2007 (72 FR 32852). The agency issued a withdrawal of a new drug application (NDA) for RAXAR (grepafloxacin hydrochloride (HCl)) Tablets held by Otsuka Pharmaceutical Co., Ltd. (Otsuka), c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850. The document published with typographical errors and cited a section of the Code of Federal Regulations that no longer exists. This document corrects those errors. The agency is also announcing the removal of RAXAR Tablets from the list of approved drug products in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations" (the Orange Book).

**DATES:** Effective July 9, 2007.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E7-11427, appearing on page 32852 in the **Federal Register** of Thursday, June 14, 2007, the following correction is made:

1. On page 32852, in the second and third columns, the **SUPPLEMENTARY INFORMATION** section is corrected to read:

**SUPPLEMENTARY INFORMATION:** In a letter dated March 5, 2003, Otsuka requested that FDA withdraw approval of NDA 20-695 for RAXAR (grepafloxacin HCl) Tablets, stating that the product was no longer being marketed. In FDA's acknowledgment letter of June 20, 2003, the agency informed Otsuka that RAXAR (grepafloxacin HCl) Tablets, indicated for the treatment of a variety of infections, had been removed from the market because of safety concerns; in its followup letter of January 12, 2007, the agency also informed Otsuka that it had determined that the RAXAR NDA should be withdrawn under § 314.150(d) (21 CFR 314.150(d)) because of its effect on cardiac repolarization, manifested as QTc interval prolongation on the electrocardiogram, which could put patients at risk of Torsade de Pointes. In its letter of March 20, 2007, Otsuka concurred in the agency's determination to initiate withdrawal of the RAXAR NDA and waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the NDA 20-695, and all amendments and supplements thereto, is withdrawn effective (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 331(d))). Also, on the basis of the circumstances described in this document that led to the withdrawal of the approval of NDA 20-695, the agency will remove RAXAR (grepafloxacin HCl) Tablets from the list of drug products with effective approvals published in the Orange Book.

Dated: June 28, 2007.

**Jeffrey Shuren,**  
Assistant Commissioner for Policy.  
[FR Doc. E7-13160 Filed 7-6-07; 8:45 am]  
BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0524]

#### Guidance for Industry on ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information." The guidance is intended to assist applicants with the submission of abbreviated new drug applications (ANDAs) when a drug substance exists in polymorphic forms.

**DATES:** Submit written or electronic comments on agency guidance documents at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Andre Raw, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9310.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls

Information.” This guidance provides: (1) A framework for making regulatory decisions on drug substance sameness in terms of polymorphic form and (2) decision trees which provide a recommended course to monitor and control polymorphs in the drug substance and/or drug product when the drug substance exists in relevant polymorphic forms.

On December 20, 2004 (69 FR 75987), the FDA announced the availability of the draft version of this guidance. The public comment period closed on March 21, 2005. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. Most of the changes to the guidance were made to clarify statements in the draft 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 pharmaceutical solid polymorphism. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

## III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-13171 Filed 7-6-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0249]

#### Draft Guidance for Industry: Preparation of Investigational Device Exemptions and Investigational New Drug Applications for Products Intended to Repair or Replace Knee Cartilage; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage” dated July 2007. The draft guidance provides to sponsors recommendations about certain information that should be included in an investigational device exemption (IDE) or investigational new drug application (IND) for a product intended to repair or replace knee cartilage. The draft guidance, when finalized, will supplement other FDA publications on IDEs and INDs.

**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 written or electronic comments on the draft guidance by October 9, 2007.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448; or the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800; or by calling CDRH at 240-276-3150 or by faxing a request to CDRH at 240-276-3151. To receive an electronic copy, send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

#### FOR FURTHER INFORMATION CONTACT:

Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210; or

Aric D. Kaiser, Center for Devices and Radiological Health (HFZ-410), 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3676.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage” dated July 2007. The draft guidance document provides to sponsors recommendations about certain information that should be included in an IDE or IND for a product intended to repair or replace knee cartilage. For the purposes of the draft guidance, a product intended to repair or replace knee cartilage, as with other articular cartilage repair or replacement products, may include a biologic, device, or combination product whose components would be individually regulated by CDRH and CBER.

FDA prepared this draft guidance to address issues that may arise in the development of articular cartilage repair or replacement products. The draft guidance also reflects input received from the public and the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) at the March 3 to 4, 2005, CTGTAC meeting. The draft guidance, when finalized, will supplement other FDA publications on IDEs and INDs.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on this topic. 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 requirement 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.