of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60 (OMB Control Number 0910–0233—Extension)

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.'' The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, nine requests for revision of the regulatory review period have been submitted under § 60.24. Four regulatory review periods have been altered. Two due diligence petitions have been submitted to FDA under § 60.30. There have been no requests for hearings under § 60.40 regarding the decisions on such petitions.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	9	1	9	100	900
60.30	2	0	2	50	100
60.40	0	0	0	0	0
Total					1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13269 Filed 7–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007C–0245]

Nippon Oil Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nippon Oil Corp. has filed a petition proposing that the color additive regulations be amended 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.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration,

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