support approval of manufacturing changes. This results in total of 14,875 burden hours.

Supplements seeking approval of changes in intended uses or conditions of use (§ 514.8(c)(1)). Over the past 3 fiscal years, October 1, 2003, through September 2006, FDA has received an average of 14 supplements annually seeking approval for changes in intended uses or conditions of use. FDA used a 3-year average for this calculation because data for the previous 2 years for this category of supplements was not tracked as an independent number. FDA estimates that it takes an average of 71 hours (approximately 1/3 of the time it takes to prepare the paperwork to support a full NADA) to prepare the paperwork to support approval for such changes. This results in a total of 994 burden hours.

Labeling Supplements (§ 514.8(c)(2) and (c)(3)). Over the past 5 fiscal years, FDA has received an average of 53 labeling supplements annually. FDA estimates that it takes an average of 20 hours (approximately 1 percent of the time it takes to prepare the paperwork to support a full NADA) to prepare the paperwork to support approval of a labeling change. This results in a total of 1,060 burden hours.

Freedom of Information Summary (§ 514.11 (21 CFR 514.11)). Regulations under § 514.11 require the preparation of a summary of the safety and effectiveness data and information submitted with or incorporated by reference in an approved NADA and that the summary be publicly released when the approval is published in the **Federal Register**. This summary, generally referred to as the Freedom of Information (FOI) Summary, may be prepared by FDA or FDA may require the applicant to prepare the summary (§ 514.11(e)(ii)). In the past, FDA has required the applicant to prepare the FOI Summary. Currently, FDA generally takes responsibility for preparing the FOI Summary. Thus, the paperwork burden on applicants to prepare an FOI Summary has significantly decreased. Based on the estimate of 19 NADAs received annually and an estimate that applicants now spend little or no time preparing the FOI summary, the estimated burden hours are 19 hours.

Requirements for liquid medicated feeds (§ 558.5(i) (21 CFR 558.5(i)). Generally, specific labeling is required to make sure that certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, are not diverted to use in liquid feeds. Section 558.5(i) permits an applicant to seek a waiver from this requirement (§ 558.5(h)) if there is evidence that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed. If FDA receives one NADA per year seeking approval of the use of a liquid medicated feed and on average it takes 5 hours to prepare the request for waiver, the estimated paperwork burden is 5 hours.

Risk assessment of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. (§§ 514.1(b)(8) and 514.8(c)(1)). FDA estimates that it receives 10 risk assessments evaluating the microbial food safety of antimicrobial new animal drugs per year. FDA estimates that it takes on average 90 hours to put together the references and other materials in the format recommended by Guidance 152 and to summarize the hazards and associated risk(s). Thus, the total burden hours for preparing such risk assessments for submission to FDA are estimated to be 900 hours.

Form FDA 356V. FDA requests that an applicant fill out and send in with NADAs and supplemental NADAs, and requests for phased review of data to support NADAs, a Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval. Over the past 5 fiscal years, FDA has received an average of 511 NADAs and supplements and 267 submissions of data to support NADAs. FDA estimates that it takes an average of 5 hours to read the instructions and fill out Form FDA 356V and organize the information that it will accompany. This results in a total of 3,890 burden hours.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13195 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–0240]

Agency Information Collection Activities; Proposed Collection; Comment Request, Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. Where a patented product must receive FDA approval before marketing is permitted, the Office of Patents and Trademarks may add a portion of the FDA review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with ''due diligence.''

DATES: Submit written comments on the collection of information by September 7, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

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]

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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,