would otherwise have an unacceptable level of risk.

Clinically relevant DDIs between an investigational drug and other drugs should therefore: (1) Be defined during drug development as part of an adequate assessment of the drug's overall benefit/risk profile; (2) be known at the time of the drug's approval; and (3) be communicated in labeling. These two final guidances are intended to assist drug developers in the planning and evaluation of DDI potential during drug development. The in vitro DDI guidance focuses on in vitro experimental approaches for evaluating metabolizing enzyme- and transporter-based drug interaction potential and how to extrapolate in vitro data to decide on the need for clinical DDI studies. The clinical DDI guidance focuses on clinical studies that evaluate DDIs that alter a drug's pharmacokinetics by modulating the effects of drug metabolizing enzymes and/or transporters and advises sponsors on the timing and design of the clinical studies, interpretation of the results, and options for DDI management in patients.

Revisions to the draft guidances include clarification on the scope of the guidances, additional considerations for prospective drug interaction studies, and when DDI studies are needed for drugs identified as transporter substrates from in vitro studies. Together, the two final guidances describe a systematic, risk-based approach to evaluation and communication of DDIs.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the current thinking of FDA on the topics they address. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

These guidances refer to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 314.50(d) have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: January 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01064 Filed 1–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–1525]

Determination That CARDENE (Nicardipine Hydrochloride) Injection, 25 Milligrams/10 Milliliters, Was 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 CARDENE (nicardipine hydrochloride) injection, 25 milligrams (mg)/10 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nicardipine hydrochloride injection, 25 mg/10 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–6650, *daniel.gottlieb@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 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, is the subject of NDA 019734, held by Chiesi USA, Inc., and initially approved on January 30, 1992. CARDENE is indicated for short-term treatment of hypertension when oral therapy is not feasible or not desirable.

In a letter dated February 13, 2018, Chiesi USA, Inc. notified FDA that CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Baxter Healthcare Corporation submitted a citizen petition on May 6, 2019 (Docket No. FDA–2019–P–1525), under 21 CFR 10.30, requesting that the Agency determine whether CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would

indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CARDENE (nicardipine hydrochloride) injection, 25 mg/10 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01062 Filed 1–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 24, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions 21 CFR Part 60

OMB Control Number 0910–0233—Extension

This information collection supports Agency regulations. 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 Generic 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. If 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 Generic 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 (USPTO) 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 USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO 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 (21 CFR 60.36) 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 petition 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.

During the calendar years 2016 through 2018, 16 requests for revision of the regulatory review period were submitted under § 60.24(a). In addition, a total of three due diligence petitions were submitted under § 60.30. There have been no requests for hearings under § 60.40; however, for purposes of this information collection approval, we estimate that we may receive one submission annually.

In the **Federal Register** of August 21, 2019 (84 FR 43606), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows: