COVID–19 guidance title	21 CFR Cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).	New collection covered by PHE PRA waiver
Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Updated).	.....	Current Good Manufacturing Practices for Finished Pharmaceuticals and Medical Gases. Postmarketing Adverse Drug Experience Reporting. MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based). Format and Content Requirements for Over-the-Counter Drug Product Labeling. FDA Adverse Event and Product Experience Reports; Electronic Submissions. Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act. Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	0910–0139 0910–0230 0910–0291 0910–0340 0910–0645	For proposed use of an alternative grade of ethanol, firms are requested to submit to FDA information on the ethanol concentration and levels of impurities listed in the USP monograph and other potentially harmful impurities in the manufacturing environment.
Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	.....	Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency. Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.	0910–0045 0910–0139 0910–0230 0910–0291 0910–0340 0910–0641 0910–0645	For proposed use of an alternative grade of ethanol, firms are requested to submit to FDA information on the ethanol concentration and levels of impurities listed in the USP monograph and other potentially harmful impurities in the manufacturing environment.

The final guidance entitled ''Policy for Certain REMS Requirements During the COVID–19 Public Health Emergency'' contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

E. Center for Veterinary Medicine

This guidance refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

COVID–19 guidance title	21 CFR Cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB Control No(s).
GFI #270—Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID–19 Public Health Emergency.	.....	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID–19 Public Health Emergency.	0910–0032 0910–0669

The final guidance entitled ''GFI #269—Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak'' contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

V. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at the FDA web page ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;* the FDA web page ''Search for FDA Guidance Documents,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or *https://www.regulations.gov.*

Dated: May 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10146 Filed 5–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1081]

Hospira Inc., et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The

applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 11, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065232	Ceftriaxone Sodium for Injection, Equivalent to (EQ) 10 grams (g) base/vial.	Hospira Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.
ANDA 088697	Amitriptyline Hydrochloride (HCl) Tablets, 10 milligrams (mg).	Par Pharmaceutical Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 088698	Amitriptyline HCl Tablets, 25 mg	Par Pharmaceutical Inc.
ANDA 088699	Amitriptyline HCl Tablets, 50 mg	Do.
ANDA 088700	Amitriptyline HCl Tablets, 75 mg	Do.
ANDA 088701	Amitriptyline HCl Tablets, 100 mg	Do.
ANDA 088702	Amitriptyline HCl Tablets, 150 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 11, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 11, 2020, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10082 Filed 5–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Nurse Faculty Loan Program—Program Specific Data Form and Annual Performance Report Financial Data Form OMB No. 0915–0314–Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 11, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Nurse Faculty Loan Program—Program Specific Data Form and Annual Performance Report Financial Data Form OMB No. 0915–0314–Revision.

Abstract: This clearance request is for approval of both the Nurse Faculty Loan Program (NFLP) Program Specific Data Form and the Annual Performance Report (APR) Financial Data Form. The APR Financial Data Form is currently approved under OMB Approval No. 0915–0314 and the Program Specific Data Form is currently approved under OMB Approval No. 0915–0378, both with the expiration date of July 31, 2020. The APR Form was previously titled as the Nurse Faculty Loan Program, Annual Operating Report. For program efficiency, HRSA is combining these previously separate ICRs under OMB No. 0915–0314 and will be discontinuing OMB No. 0915–0378.

A 60-day notice published in the **Federal Register** on February 7, 2020, vol. 85, No. 26; pp. 7315–7316. There were no public comments.

Need and Proposed Use of the Information: Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to enter into an agreement with schools of nursing for the establishment and