FOR FURTHER INFORMATION CONTACT: Natalie Grant, Director, Office of Human Services Emergency Preparedness and Response, 330 C St. SW, Washington, DC 20201. Telephone: 202–205–7843; Email: *Natalie.grant@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: OHSEPR announces the intent to award the following single-source awards:

Recipient	Award amount of up to
United Way Worldwide, Alexandria, VA	$75,000
National Association of Social Workers, Washington, DC	75,000
American Public Human Services Association, Arlington, VA	75,000
National Association of County Human Services Administrators, Washington, DC	75,000

United Way supports 211, which is the most comprehensive source of information about local resources and services in the United States. United Way's 211 has demonstrated experience providing disaster-related assistance to disaster survivors. United Way's existing network of 211 agencies will provide information and referrals to evacuees from Afghanistan including repatriates eligible for temporary assistance.

NASW is the largest membership organization of professional social workers in the world. NASW has the ability to train a large number of professional social workers across the United States, including many who have provided case management and human services following an emergency. NASW will train its members on how to provide culturally competent case management and human services to evacuees from Afghanistan and ensure appropriate coordination and subject matter expertise.

APHSA is a national membership association representing state and local health and human services agencies and subject matter experts who help execute their mission. APHSA has a direct connection to a network of state and county health and human services executives with first-hand knowledge of and expertise in operating programs and delivering human services following an emergency. APHSA will educate its members on the provision of culturally appropriate human services to evacuees from Afghanistan by providing training and technical assistance.

NACHSA members represent a broad range of human services agencies throughout the United States, including ones that provide public assistance, child care, child protective services, and adult protective services. NACHSA supports the professional development of county human services administrators, whose agencies deliver essential human services. NACHSA will educate its membership on providing culturally appropriate human services to evacuees from Afghanistan and ensure county level coordination of services.

Statutory Authority: Social Security Act, Title XI, Part A, Section 1113, 42 U.S. Code 1313(a)(3).

Elizabeth Leo,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2021–21418 Filed 9–28–21; 4:15 pm]

BILLING CODE 8414–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0492]

Watson Laboratories, Inc., et al.; Withdrawal of Approval of 36 Abbreviated New Drug Applications; 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 25, 2021. The document announced the withdrawal of approval of 36 abbreviated new drug applications (ANDAs) from multiple applicants as of July 26, 2021. The document indicated that FDA was withdrawing approval of the following ANDA, after receiving a withdrawal request from Yung Shin Pharmaceutical Ind. Co. Ltd., authorized U.S. agent, Carlsbad Technology, Inc./ Simon Law, 5922 Farnsworth Ct., Suite 101, Carlsbad, CA 92008: ANDA 065152, Cephalexin Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base. Before FDA withdrew the approval of this ANDA, Yung Shin Pharmaceutical Ind. Co. Ltd. informed FDA that it did not want the approval of the ANDA withdrawn. Because Yung Shin Pharmaceutical Ind. Co. Ltd. timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 065152 is still in effect.

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: In the **Federal Register** of Friday, June 25, 2021 (86 FR 33718), FR Doc. 2021–13593, the following correction is made:

On page 33718, in the table, the entry for ANDA 065152 is removed.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21371 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 requests comments on the information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities and related human prescription drug compounding businesses. The research supports a comprehensive analysis of the outsourcing facility sector that informs ongoing FDA work in this area.

DATES: Submit either electronic or written comments on the collection of information by November 30, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 30, 2021. The *https://www.regulations.gov* electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of November 30, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3077 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

OMB Control Number 0910–0883—Extension

This information collection supports FDA research in obtaining a range of information pertaining to human prescription drug compounding by outsourcing facilities. Generally, drug compounding is the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored an individual patient's needs. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, compounded drugs also present a risk to patients. Compounded drugs are not FDA-approved; therefore, they do not undergo FDA premarket review for safety, effectiveness, and quality. Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for compounded human prescription drug products to be exempt from certain sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B))

(current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (approval of drugs under new drug applications or abbreviated new drug applications).

The Drug Quality and Security Act of 2013 (Pub. L. 113–54) created outsourcing facilities—a new industry sector of drug compounders held to higher quality standards to protect patient health. Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that outsourcing facilities must satisfy for drug products compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist to be exempt from the certain sections of the FD&C Act. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs that hospitals, clinics, and other providers need.

FDA continues to find concerning quality and safety problems during inspections of outsourcing facilities. FDA has implemented and will continue to implement programs to support compounding quality and compliance. One initiative is FDA's Compounding Quality Center of Excellence (Center of Excellence), *https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence, which was* developed to focus on improving the quality of compounded human prescription drugs to promote patient safety. One of our top priorities is to help ensure that compounded drugs are safe by focusing on quality. FDA, state regulators, pharmacy associations, and compounders, including outsourcing facilities, share the responsibility of patient safety.

The Center of Excellence engages and collaborates with compounders, including outsourcing facilities, and other stakeholders to improve the overall quality of compounded drugs. Furthermore, the Center of Excellence promotes collaboration to help compounders implement robust quality management systems that are better for business and the safety of patients.

To help strengthen the outsourcing facility industry's ability to provide quality compounded drugs to patients who need them, the Center of Excellence offers training sessions and opportunities to develop manufacturing quality and other policies for outsourcing facilities, including CGMPs.

The Center of Excellence offers several training sessions (available at *https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence-training-programs*). Self-guided training sessions teach the following topics: (1) Environmental monitoring, (2) sterile drug compounding, (3) cleanroom performance tests, and (4) conducting investigations and formulating corrective and preventive actions. Instructor-led sessions teach the regulatory framework for these topics: (1) Human drug compounding, (2) airflow practices, (3) insanitary conditions and sterility, (4) stability and beyond use dates, (5) requirements for outsourcing facility guides, and (6) conducting investigations and formulating corrective and preventive actions. Management and staff from outsourcing facilities have attended the training sessions. Feedback on the training sessions has been positive, and interest in the sessions continues to grow.

In addition, the Center of Excellence is conducting indepth research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement. Outsourcing facilities encounter the following challenges and opportunities: (1) Operational barriers and opportunities related to the outsourcing facility market and business viability, (2) knowledge and operational barriers and opportunities related to compliance with Federal policies and good quality drug production, and (3) barriers and opportunities related to outsourcing facility interactions with FDA.

FDA used previous research results under this information collection to develop an understanding of the outsourcing facility sector, the sector's challenges, and opportunities for advancement. The information collected was an essential tool to help FDA identify knowledge and information gaps, operational barriers, and views on interactions with FDA. FDA has presented this information in public settings such as stakeholder meetings. Continuing this collection will enable FDA to deepen our understanding of the outsourcing facility sector and increase our efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs. The research results will inform FDA's future activities for the Center of Excellence in the areas of communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers engage with pharmacists, staff, and management from outsourcing facilities and similar compounding businesses and may use surveys, interviews, and focus groups to obtain information about outsourcing facilities' challenges and opportunities. Within this context, we may pose the following questions or similar, related questions:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?

2. What factors impact developing a sustainable outsourcing facility business?

3. What financial and operational considerations inform outsourcing facility product decisions?

4. Do outsourcing facilities understand the Federal laws and policies that apply to them? What, if any, knowledge gaps do we need to address?

5. What are outsourcing facilities' challenges when implementing Federal CGMP requirements?

6. How do outsourcing facilities implement quality practices at their facilities?

7. How do outsourcing facilities develop CGMP and quality expertise? How do they obtain this knowledge, and what training do they need?

8. What are the economic consequences of CGMP noncompliance and product failures for outsourcing facilities?

9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?

10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

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

Our original request for the information collection was approved January 21, 2020; however, the subsequent public health emergency inhibited our ability to administer the requested survey. We have therefore made no adjustments to our current burden estimate.

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21382 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

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: Submit written comments (including recommendations) on the collection of information by November 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0805. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2020, approximately 474 user fee refunds were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 0 for Export Certificate Program fees, 0 for Freedom of Information Act requests, 31 for Generic Drug User Fees, 200 for Medical Device User Fees, 240 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer requests.

In fiscal year 2020, approximately 194 user fee payment transfers were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 34 for Generic Drug User Fees, 78 for Medical Device User Fees, 80 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, biological, medical device firms, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Respondents