comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 9, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Heather Hippsley,

Acting Principal Deputy General Counsel.

[FR Doc. 2018–16936 Filed 8–7–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–1072]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Enhanced STD surveillance Network (SSuN) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March, 15, 2018 to obtain comments from the public and affected agencies. CDC received 37 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Enhanced STD surveillance Network (SSuN)—Reinstatement with Change—Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Enhanced STD surveillance network project was created to provide enhanced behavioral, demographic, and clinical information on gonorrhea cases reported to state and local health departments, to provide information on patients presenting for care in STD clinical settings, and to provide an infrastructure for identifying emerging sequelae of STDs.

Enhanced SSuN continues to be a collaboration between different branches of the CDC Division of STD Prevention and selected state/local public health departments and their associated STD specialty care clinics in the US. Data from enhanced SSuN data is used to (1) provide a dataset of supplemental information on gonorrhea case reports; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs, (3) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in populations of interest, (4) monitor STD treatment and prevention service practices, and (5) monitor selected adverse health outcomes of STDs, including neuro/ocular syphilis,

This project will continue to utilize two distinct surveillance strategies to collect information. The first strategy employs facility-based sentinel surveillance, which will abstract routine standardized data from existing electronic medical records for all patient visits to participating STD clinics during the project period. For the facility-based component of enhanced SSuN, participating sites have developed common protocols stipulating data elements to be collected, including patient demographics, clinical, risk and sexual behaviors. The specified data elements are abstracted by clinic staff from

existing electronic medical records for all patient visits to participating STD clinics. Some of the participating facilities are satellite clinics of large network providers where clinical data systems are centralized. Hence, there are 10 unique clinic data managers that will be abstracting the facility data. Each of the clinic data managers will spend three hours to extract and transmit data to local/state health departments. Individual patient records are de-identified (all patient-specific identifiers are removed) by clinic staff before being transmitted to health departments, who recode the data into standardized formats before being transmitted to CDC through secure file transport mechanisms. Each enhanced SSuN site will spend 16 hours to recode and transmit the data to CDC every other month. At CDC, data will be aggregated across all participating sites in a common data structure and formatted for analysis.

Under this revision, the second strategy, population-based STD surveillance is being expanded to include not only a random sample of reported gonorrhea cases but also include patients diagnosed with early syphilis that report neurologic/ocular manifestations. For the gonorrhea population component, a probability sample of gonorrhea cases (up to 10% of total gonorrhea morbidity for participating jurisdictions) will be contacted by health department staff for a standardized interview either by phone or in-person. Enhanced gonorrhea investigations will also include verification of treatment and an internal health department record review (performed on either all cases or on the sampled cases). The focus of the new population activity focuses on obtaining additional clinical information on early syphilis cases who report neurologic/ocular symptoms. The subset of patients reporting these symptoms are asked to participate in an interview to obtain additional clinical information for a more complete assessment of neurologic/ocular involvement as well as obtain additional clinical information from the diagnosing or reporting provider. Lastly, early syphilis cases reporting neurologic and/or ocular symptoms are recontacted at approximately three months following prescribed treatment to ascertain whether initial symptoms have resolved.

The population data will be directly entered into existing STD surveillance information systems at each health department. Data will be locally extracted, de-identified and recoded into standardized formats prior to being transmitted to CDC through secure file transport mechanisms on bimonthly basis. Patient participation in the interview is voluntary and refusal to participate has no impact on other STD services the health department provides to persons diagnosed with gonorrhea.

This project will not collect name, social security number, or date of birth. A Patient ID, a unique patient identifier assigned by the clinic or health department depending on the component, is requested and will be provided to CDC for purposes of enhanced surveillance. Patient IDs are not linkable across enhanced SSuN components. Sensitive information such as sex of sex partners, HIV status, sex work exposure, and injection drug use are collected. All personally identifiable information (PII) is retained by the STD clinics and/or health departments and is not recorded with data sent to CDC. The electronic enhanced SSuN database is stored on the CDC mainframe computer and only approved Division of STD Prevention (DSTDP) staff have access rights to the data. As part of the revision, we will continue to systematically identify the risks and potential effects of collecting, maintaining, and disseminating PII and to examine and evaluate alternative processes for handling that information to mitigate potential privacy risks and risks to confidentiality.

Both components of enhanced SSuN are designed to (1) Integrate traditional surveillance methods with innovative data management technologies to produce high-quality, timely surveillance and epidemiologic data, (2) provide valuable information to direct public health STD prevention and control efforts, (3) enhance understanding of the community burden of disease, (4) identify syndemic patterns and population at greatest risk, and, (5) monitor long-term health consequences of STDs. The enhanced SSuN surveillance platform allows CDC to establish and maintain common standards for data collection, transmission, and analysis, and to build and maintain STD surveillance expertise in 10 state/local health departments. Such common systems, established mechanisms of communication, and in-place expertise are all critical components for timely, flexible, and high quality surveillance. The total estimated annual burden is 3,479 hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Data manager at Sentinel STD clinics	Record Abstraction	10	6	3
General Public—Adults (persons diagnosed and reported with gonorrhea or early syphilis.	Interview	5492	1	10/60
Diagnosing Provider	Data for early syphilis cases	406	1	10/60
General Public—Adults (persons with early syphilis who were reported with neurologic/ocular manifestations.	3 month follow-up telephone Interview	203	1	5/60
Data Managers: 10 local/state health department.	Data cleaning/validation/reformatting	10	12	19

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–16947 Filed 8–7–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2485]

Fougera Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 27 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 27 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications 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 September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The holders of the applications 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 061467	Pyocidin-Otic (hydrocortisone and polymyxin B sulfate) Otic Solution, 5 milligrams (mg)/10,000 units per milliliter (mL).	Fougera Pharmaceuticals, Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
ANDA 061653	Tetrex (tetracycline phosphate complex) Capsules, Equivalent to (EQ) 100 mg Hydrochloride (HCl), EQ 250 mg HCl and EQ 500 mg HCl.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
ANDA 061658	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061711	Penicillin V Potassium Tablets	Do.
ANDA 061721	Ampicillin Capsules, 250 mg and 500 mg	Do.
ANDA 061726	Azotrex (phenazopyridine HCl, sulfamethizole and tetracycline phosphate complex) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061790	Hetacillin Potassium	Do.
ANDA 061887	Bristamycin (erythromycin stearate) Tablets, EQ 250 mg base	Do.
ANDA 061888	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061889	Tetrex (tetracycline phosphate complex) Capsules, EQ 250 mg HCl and EQ 500 mg HCl.	Do.
ANDA 061890	Azotrex (phenazopyridine HCl, sulfamethizole, and tetracycline) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061891	Tetrex-S (tetracycline) Syrup, 125 mg/5 mL	Do.
ANDA 061975	Cephradine Powder for Injection	Do.
ANDA 062168	Cephradine Tablets	Do.
ANDA 062259	Amphotericin B for Use in Parenteral Products	Do.
ANDA 062543	Mycolog (nystatin, neomycin sulfate, gramicidin, and triamcinolone acetonide) Ointment.	Do.
ANDA 071793	Foamcoat (aluminum hydroxide; magnesium trisilicate) Chewable Tablets, 80 mg/20 mg (OTC).	Guardian Drug Co., 2 Charles Court, Dayton, NJ 08810.
ANDA 072035	Nuprin (ibuprofen) Tablets, 200 mg	Bristol-Myers Squibb Co.
ANDA 072036	Nuprin (ibuprofen) Tablets, 200 mg	Do.
ANDA 074911	Phrenilin with Caffeine and Codeine (acetaminophen, butalbital, caffeine, and codeine phosphate) Capsules, 325 mg/50 mg/40 mg/30 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 074944	Atracurium Besylate Injection, 10 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075206	Cytosar-U (cytarabine) for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram (g)/vial, and 2 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 077337	Rosiglitazone Maleate and Metformin HCl Tablets, EQ 1 mg base/500 mg, EQ 2 mg base/500 mg, EQ 4 mg base/500 mg, EQ 2 mg base/1 g, and EQ 4 mg base/1 g.	Do.
ANDA 077930	Meloxicam Tablets, 7.5 mg and 15 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 080658	Procaine HCl Injection, 1% and 2%	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083128	Hydrocortisone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 090181	Ifosfamide for Injection, 1 g/20 mL and 3 g/60 mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.