history and are potential applicants for Supplemental Security Income (SSI).

The NextGen Project will use a two-phased approach for approval of this proposed information collection activity. In Phase 1 (current request) the research team seeks approval to formally recruit programs, to administer the informed consent form and baseline participant survey, and to collect identifying and contact information for study participants. The project intends for these data collections to be uniform across programs selected for evaluation and it does not anticipate that they will require revisions.

Under Phase 2 of the request, the project will update the information collection request for the remaining instruments to tailor to each program selected for the evaluation, as needed.

The proposed information collection activities cover an experimental impact study, descriptive study, and cost study. Data collection activities for the impact study include: (1) Baseline survey and identifying and contact information data collection, (2) a first follow-up survey, and (3) a second follow-up survey. Data collection activities for the descriptive study include: (1) Service receipt tracking; (2) staff characteristics survey; (3) program leadership survey; (4) semi-structured program discussion guide (conducted with program leaders, supervisors, partners, staff, and providers); (5) semi-structured employer discussion guide (for those interventions that include an employer component); and (6) in-depth participant interviews. Data collection activities for the cost study include an Excel-based cost workbook.

Respondents: Program staff, program partners, employer staff, and individuals enrolled in the NextGen Project. Program staff and partners may include case managers, health professionals, workshop instructors, job developers, supervisors, managers, and administrators. Employers may include administrators, human resources staff, and worksite supervisors.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
PHASE 1					
Baseline survey & identifying and contact information—participants	10,000	3,333	1	0.42	1,400
Baseline survey & identifying and contact information—staff	200	67	50	0.42	1,407
Estimated Total Annual Burden Hours, Phase 1:					2,807
PHASE 2 ESTIMATES					
First follow-up survey—participants	8,000	2,667	1	0.83	2,214
Second follow-up survey—participants	8,000	2,667	1	0.83	2,214
Service receipt tracking—program staff	200	67	250	0.08	1,340
Staff characteristics survey—program staff	200	67	1	0.42	28
Program leadership survey—program leaders	50	17	1	0.25	4
Semi-structured program discussion guide—program leaders	40	13	1	1.5	20
Semi-structured program discussion guide—program supervisors and partners	80	27	1	1.0	27
Semi-structured program discussion guide—program staff, providers	80	27	1	0.75	20
Semi-structured employer discussion guide—employers	50	17	1	1.0	17
In-depth participant interview guide—participants	200	67	1	2.0	134
Cost workbook—program staff	40	13	1	32.0	416
Estimated Total Annual Burden Hours, Phase 2:					6,434

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Public Law 115–31).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–00107 Filed 1–7–20; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0764]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Feed Regulatory Program Standards

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 7, 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 0910–0760. 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.

Animal Feed Regulatory Program Standards

OMB Control Number 0910–0760—Extension

I. Background

In the United States, Federal and State Government Agencies ensure the safety of animal feed. FDA is responsible for ensuring that all food and feed moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of feed facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed.

The FDA Food Safety Modernization Act (Pub. L. 111–353) passed on January 4, 2011, calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of food and feed safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal Agencies to ensure credibility of food and feed programs within the IFSS.

II. Significance of Feed Program Standards

The Animal Feed Regulatory Program Standards (AFRPS) provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards is voluntary. States implementing the standards will identify and maintain program improvements that will strengthen the safety and integrity of the U.S. animal feed supply.

The feed standards are the framework that each State should use to design, manage, and improve its feed program. The standards include the following: (1) Regulatory foundation; (2) training; (3) inspection program; (4) auditing; (5) feed-related illness or death and emergency response; (6) enforcement program; (7) outreach activities; (8) budget and planning; (9) assessment and improvement; (10) laboratory services; and (11) sampling program.

Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a State program voluntarily agrees to implement the feed standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard.

The feed standards package includes forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates provided with the feed standards. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the feed standards must be maintained in good order by the State program and must be available to verify the implementation of each standard. The feed standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

As set forth in the feed standards, the State program is expected to review and update its improvement plan on an annual basis. The State program completes an evaluation of its implementation status at least every 3 years following the baseline evaluation by reviewing and updating the self-assessment worksheets and required documentation for each standard. The evaluation is needed to determine if each standard's requirements are, or remain, fully met, partially met, or not met. The State program revises the improvement plan based upon this evaluation.

Although FDA plans to provide financial support to State programs that implement the feed standards, funding opportunities are contingent upon the availability of funds. Funding opportunities may be only available to State feed regulatory programs that currently have an FDA feed inspection contract. State programs receiving financial support to implement the feed standards will be audited by FDA.

III. Electronic Access

Persons with access to the internet may submit requests for a single copy of the current feed standards from *OP-PRA@fda.hhs.gov.*

In the **Federal Register** of September 20, 2019 (84 FR 49524), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was submitted but did not address any of the topics solicited and we therefore do not discuss the comment here.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Animal Feed Regulatory Program in the United States	34	1	34	569	19,346

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

Respondents to the information collection are State agencies seeking to avail themselves of the options described in the document. State agencies that conduct feed inspections under contract are interested in implementing the standards. The total estimated annual recordkeeping burden for implementation is 569 hours per respondent. The burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 11 standards contained in the AFRPS. The hours per State feed regulatory program will average the same to account for continual improvement and self-sufficiency in the program. Our burden estimate reflects a decrease of 100,654 hours as a result of fewer respondents to the collection and a reevaluation of the time we ascribe for recordkeeping activities.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00073 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5550]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 23 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 23 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 February 7, 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 040448	Phentermine Hydrochloride (HCl) Capsules USP, 30 milligrams (mg).	Elite Laboratories, Inc., 165 Ludlow Ave., Northvale, NJ 07647.
ANDA 060272	E-Mycin (erythromycin) Delayed-Release Tablets USP, 250 mg and 333 mg.	Arbor Pharmaceuticals, LLC, 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.
ANDA 061639	E.E.S. 200 (erythromycin ethylsuccinate) for Oral Suspension, Equivalent to (EQ) 200 mg base/5 milliliters (mL).E.E.S. 400 (erythromycin ethylsuccinate) for Oral Suspension, EQ 400 mg base/5 mL.	Do.
ANDA 062290	EryDerm (erythromycin) Topical Solution USP, 2%	Arbor Pharmaceuticals, LLC.
ANDA 062304	Pediamycin (erythromycin ethylsuccinate) Oral Suspension USP, EQ 200 mg base/5 mL Pediamycin 400 (erythromycin ethylsuccinate) Oral Suspension USP, EQ 400 mg base/5 mL.	Do.
ANDA 062659	Claforan ADD-Vantage (cefotaxime) for Injection USP, EQ 1 gram (g) base/vial and EQ 2 g base/vial.	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
ANDA 070347	Hydro-Ride (amiloride HCl and hydrochlorothiazide) Tablets, EQ 5 mg Anhydrous/50 mg.	Par Pharmaceutical, Inc., One Ram Ridge Rd., Spring Valley, NY 10977.
ANDA 071142	Clonidine HCl and Chlorthalidone Tablets USP, 0.3 mg/15 mg.	Do.
ANDA 071178	Clonidine HCl and Chlorthalidone Tablets USP, 0.2 mg/15 mg.	Do.
ANDA 071179	Clonidine HCl and Chlorthalidone Tablets USP, 0.1 mg/15 mg.	Do.
ANDA 073191	Triamterene and Hydrochlorothiazide Capsules USP, 50 mg/25 mg.	CASI Pharmaceuticals, Inc., c/o Target Health, Inc., 261 Madison Ave., 24th Floor, New York, NY 10016.
ANDA 073416	E–Z Scrub (chlorhexidine gluconate) Sponge, 4%	Becton, Dickinson and Co., 9450 South State St., Sandy, UT 84070.
ANDA 076075	Econazole Nitrate Cream, 1%	CASI Pharmaceuticals, Inc., c/o Target Health, Inc.
ANDA 076192	Ribavirin Capsules USP, 200 mg	Do.
ANDA 076514	Midodrine HCl Tablets USP, 2.5 mg, 5 mg, and 10 mg	Do.