

SUMMARY: The Office of Planning, Research, and Evaluation and the Family and Youth Services Bureau (FYSB) in the Administration for Children and Families propose data collection activities as part of the Sexual Risk Avoidance Education (SRAE) Program Performance Analysis Study (PAS). The goal of the study is to collect, analyze, and report on performance measures data for SRAE programs.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment

is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA.SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE

Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Description: The purpose of the SRAE program is to educate youth on “how to voluntarily refrain from non-marital sexual activity and prevent other youth risk behaviors.” Data will be used to determine if the SRAE grantees are meeting performance benchmarks related to their program’s mission and priorities.

Respondents: Departmental (DSRAE), State (SSRAE), and Competitive (CSRAE) grantees, their subawardees, and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondents	Average burden hours per response	Annual burden hours
(1) Participant Entry Survey					
DSRAE participants	161,916	53,972	1	0.1333	7,195
SSRAE participants	1,108,456	369,485	1	0.1333	49,252
CSRAE participants	29,108	9,703	1	0.1333	1,293
(2) Participant Exit Survey					
DSRAE participants	129,948	43,316	1	0.2667	11,552
SSRAE participants	886,768	295,589	1	0.2667	78,834
CSRAE participants	22,871	7,624	1	0.2667	2,033
(3) Performance Reporting Data Entry Form—Grantees					
DSRAE grantees	150	50	2	16	1,600
SSRAE grantees	117	39	2	16	1,248
CSRAE grantees	144	48	2	16	1,536
(4) Performance Reporting Data Entry Form—Sub Awardees					
DSRAE subawardees	3,450	1,150	2	13	29,900
SSRAE subawardees	2,700	900	2	13	23,400
CSRAE subawardees	831	277	2	13	7,202

Estimated Total Annual Burden Hours: 215,045.

Authority: 42 U.S.C. 1310.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-10762 Filed 5-22-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1524]

**Bedford Laboratories, et al.;
Withdrawal of Approval of 24
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 24 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 24, 2019.

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 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 040524	Promethazine Hydrochloride (HCl) Injection USP, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 070857	Trazodone HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070987	Diazepam Tablets USP, 2 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 070996	Diazepam Tablets USP, 5 mg	Do.
ANDA 071717	Flurazepam HCl Capsules USP, 15 mg and 30 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 071751	Methyldopa Tablets USP, 125 mg	Halsey Drug Co., Inc.
ANDA 071752	Methyldopa Tablets USP, 250 mg	Do.
ANDA 077190	Milrinone Lactate Injection, EQ 1 mg base/mL	Gland Pharma, Ltd., c/o INC Research, LLC, 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609.
ANDA 077703	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial.	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 080300	Prednisone Tablets USP, 5 mg	Halsey Drug Co., Inc.
ANDA 080961	Chlorpheniramine Maleate Tablets USP, 4 mg	Aurolife Pharma, LLC.
ANDA 083453	Niacin Tablets USP, 500 mg	Halsey Drug Co., Inc.
ANDA 083629	Kloromin (chlorpheniramine maleate) Tablets USP, 4 mg.	Do.
ANDA 083930	Dextroamphetamine Sulfate Tablets USP, 10 mg	Do.
ANDA 084676	Secobarbital Sodium Capsules USP, 100 mg	Do.
ANDA 085088	Hydralazine HCl Tablets USP, 50 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 085219	Hydrochlorothiazide Tablets, 50 mg	Aurolife Pharma, LLC.
ANDA 085923	Amitriptyline HCl Tablets USP, 10 mg	Halsey Drug Co., Inc.
ANDA 087279	Butalbital, Aspirin, and Caffeine Tablets	Sandoz, Inc., 227-15 North Conduit Ave., Laurelton, NY 11413.
ANDA 088116	Myfed (pseudoephedrine HCl and triprolidine HCl) Syrup, 30 mg/5 mL and 1.25 mg/5 mL.	USL Pharma, LLC, 301 South Cherokee St., Denver, CO 80223.
ANDA 088725	Chlorpropamide Tablets USP, 100 mg	Aurolife Pharma, LLC.
ANDA 089130	Hydralazine HCl Tablets USP, 25 mg	Halsey Drug Co., Inc.
ANDA 089178	Hydralazine HCl Tablets USP, 100 mg	Do.
ANDA 201484	Levofloxacin Tablets, 250 mg, 500 mg, and 750 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 24, 2019. Approval of each entire application is withdrawn, including any strengths or products 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 24, 2019, 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 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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; Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915-0298—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of 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 will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 24, 2019.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

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: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915-0298—Revision.