departments, including six new and 18 continuing awardees from the previous NOFO. Key program elements were retained (*e.g.,* provision of screening services, promotion of healthy lifestyle behaviors, and linkage to healthy behavior support services and community based resources), but a number of changes were incorporated into the program at that time. The current FOA reflects increased emphasis on three strategies to reduce CVD risk and support hypertension control and management, including: (1) Tracking and monitoring clinical measures, (2) implementing team-based care, and (3) linking community resources and clinical services to support care coordination, self-management, and lifestyle change.

CDC seeks to conduct a one-time, multi-component evaluation to assess the effectiveness of the program on individual-, organizational-, and community-level outcomes. The in-depth assessment is designed to complement the routine progress and MDE information already being collected from WISEWOMAN program recipients. The new data collection will focus on obtaining qualitative and quantitative information at the organizational and community levels about process and procedures implemented, and barriers, facilitators, and other contextual factors that affect program implementation and participant outcomes. Data collection activities will include a Program Survey with all WISEWOMAN awardee programs, administered in the second and fourth program years, and a one-time site visit to each recipient spread across the three-year data collection effort. During site visits, semi-structured interviews will be conducted with WISEWOMAN staff members and staff at partner organizations, such as clinical providers and community-based resource providers, who are positioned to provide a variety of perspectives on program implementation.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The estimated annual burden is 84 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
WISEWOMAN Recipient Administrators	Program survey	18	1	1
	Site Visit Discussion Guide	8	1	90/60
	Innovation Site Visit Discussion Guide	2	1	45/60
Recipient partners	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60
Healthy behavior support staff	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60
Clinical providers	Site Visit Discussion Guide	16	1	1
	Innovation Site Visit Discussion Guide	2	1	45/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23018 Filed 10–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4466]

Determination That PROAMATINE (Midodrine Hydrochloride) Tablets, 2.5 Milligrams, 5 Milligrams, and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PROAMATINE (midodrine hydrochloride) tablets, 2.5 milligrams (mg), 5 mg, and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows FDA to approve abbreviated new drug applications (ANDAs) for midodrine hydrochloride tablets, 2.5 mg, 5 mg, and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.

PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, is the subject of NDA 019815, held by Shire Development LLC (Shire), and initially approved on September 6, 1996, under the accelerated approval process (see 21

CFR 314.510). PROAMATINE is indicated for the treatment of orthostatic hypotension. PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Shire no longer markets PROAMATINE in any strength; although there are approved ANDAs referencing NDA 019815, PROAMATINE has been withdrawn from sale.

We have carefully reviewed our files for records concerning the withdrawal of PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. FDA has determined under § 314.161 that PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, FDA will continue to list PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. We note that, because PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, were approved under the accelerated approval pathway, Shire was required to conduct post-approval studies to verify the clinical benefit of PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg. The clinical benefit of PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, remains subject to verification.

ANDAs that refer to PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23014 Filed 10–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice To Announce Project Period Extensions With Funding for Health Center Program Award Recipients in Pago Pago, American Samoa; Bishop, California; Baltimore, Maryland; and Worcester, Massachusetts

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

ACTION: Notice.

SUMMARY: Additional grant funds were provided to four Health Center Program award recipients with project periods ending in fiscal year (FY) 2019 to extend their project periods by up to four months to ensure the ongoing delivery of services until a new award could be made.

SUPPLEMENTARY INFORMATION:

Recipients of the Award: Four award recipients, as listed in Table 1, in Pago Pago, American Samoa; Bishop, California; Baltimore, Maryland; and Worcester, Massachusetts.

Amount of Non-Competitive Awards: $3,066,387.

Period of Supplemental Funding: FY 2019.

Assistance Listings (CFDA) Number: 93.224.

Authority: Public Health Service Act, Section 330, as amended (42 U.S.C. 254b, as amended).

Justification: HRSA extended the FY 2019 project periods with prorated supplemental grant funds to four award recipients by up to four months until a new award is made for each service area. Continued funding to the Health Center Program award recipients ensured that individuals in the service areas received uninterrupted access to needed health care services. The approvals enabled HRSA to support consistent health care to beneficiaries, eliminate delays in funding gaps, and demonstrate administrative efficiencies. HRSA awarded approximately $3 million to the four existing Health Center Program award recipients noted in Table 1.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Extension length (months)	Award amount
H80CS02470	American Samoa Government Department of Health.	Pago Pago, American Samoa	3	$775,917
H80CS26629	Toiyabe Indian Health Project, Inc	Bishop, California	4	382,549
H80CS00067	Parkwest Health Systems, Inc	Baltimore, Maryland	4	1,326,373
H80CS00003	Community Healthlink, Inc	Worcester, Massachusetts	4	581,548

FOR FURTHER INFORMATION CONTACT: Olivia Shockey, Expansion Division Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, at *oshockey@hrsa.gov* or 301–594–4300.

Dated: October 8, 2019.

Thomas J. Engels,

Acting Administrator.

[FR Doc. 2019–22984 Filed 10–21–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

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

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.