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markets PROAMATINE in any strength; although there are approved ANDAs referencing NDA 019815, PROAMATINE has been withdrawn from sale.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FDA has determined under § 314.161 that PROAMATINE (midodrine hydrochloride) tablets, 2.5 mg, 5 mg, and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness.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.