contact Linda Tavener at 410–786–3838).

Dated: November 12, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–27135 Filed 11–14–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcing the Award of a Single-Source Program Expansion Supplement Grant to the Futures Without Violence in San Francisco, CA

AGENCY: Family and Youth Services Bureau, ACYF, ACF, HHS.

ACTION: Notice of the award of a single-source program expansion supplement grant under the Family Violence Prevention and Services Act (FVPSA) Technical Assistance (TA) Project to the Futures Without Violence to support training and technical assistance activities.

CFDA Number: 93.592.

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB), Division of Family Violence Prevention and Services (DFVPS) announces the award of $270,000 as a single-source program expansion supplement to Futures Without Violence in San Francisco, CA. The grantee, funded under the Family Violence Protection and Services Act (FVPSA) program, is a technical assistance (TA) provider that serves as the FVPSA-funded National Health Resource Center on Domestic Violence.

DATES: The period of support is September 30, 2014 through September 29, 2015.

FOR FURTHER INFORMATION CONTACT: Shawndell Dawson, Senior Program Specialist, Family Violence Prevention and Services Program, 1250 Maryland Avenue SW., Suite 8219, Washington, DC 20024. Telephone: 202–205–1476; Email: *Shawndell.Dawson@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Supplemental award funds will support the grantee in providing training and technical assistance to domestic violence service and health care providers. A portion of the supplemental award is contributed by the Health Resources and Services Administration (HRSA) and the Office on Women's Health (OWH) at the Department of Health and Human Services (HHS).

This award will expand the scope of Futures Without Violence's technical assistance activities to include additional activities on the following issues: Assessing and responding to domestic violence in health clinics; addressing dating violence and sexual assault on college campuses; and supporting children/youth experiencing domestic violence. This additional technical assistance and training may involve such activities as:

- Planning, coordinating, and evaluating a pre-conference institute on Sexual Assault and Dating Violence on College Campuses, as part of the 2015 National Conference on Health and Domestic Violence;
- providing technical assistance for three health centers to create health system changes that support providers and create sustainable responses to victims of intimate partner violence;
- providing training on comprehensive, culturally competent responses to domestic violence within a Patient Centered Medical Home model.
- creating new technical assistance resources that promote protective factors and resilience when working with children, youth, and teens impacted by domestic violence which includes fostering stronger relationships with their non-abusive parents or caregivers;
- providing training to domestic violence programs that improves consistent implementation of evidence-informed, trauma-informed, and culturally relevant programming for children, youth, and abused parents; and,
- developing new resources for the Web site, *www.PromisingFuturesWithoutViolence.org.*

Statutory Authority: The statutory authority for the FVSPA Program is under section 310 of the FVPSA, as amended by Section 201 of the CAPTA Reauthorization Act of 2010, Pub. L. 111–320. The Office on Women's Health authority for its additional funds is through Sections 1701(a)(3)(A), 1701(a)(5), and 1701(a)(8) of the Public Health Service Act; and the Economy Act (31 U.S.C. 1535/FAR 17.5). HRSA's authority for its funds is through Section 330 of the Public Health Service Act (42 U.S.C. § 254b).

Christopher Beach,

Senior Grants Policy Specialist, Office of Administration, Office of Financial Services, Division of Grants Policy.

[FR Doc. 2014–27131 Filed 11–14–14; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1461]

Rare Pediatric Disease Priority Review Vouchers, Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Rare Pediatric Disease Priority Review Vouchers.'' Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA will award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the criteria specified in that section. These vouchers can be used when submitting future human drug marketing applications that would not otherwise qualify for priority review. These vouchers can be sold or transferred for use to another sponsor any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. Because there exists a need for products for rare pediatric diseases, this program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 16, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by January 16, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 3128, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; or Office of Orphan Products Development, Office of Special Medical Programs,

Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office that will be processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Henry Startzman, Food and Drug Administration, Office of Orphan Products Development, Bldg. 32, Rm. 5295, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Rare Pediatric Disease Priority Review Voucher.''

This draft guidance clarifies FDA's plans to implement section 908 of the Food and Drug Administration Safety and Innovation Act (FDASIA), which added section 529 to the Federal Food Drug and Cosmetic Act (21 U.S.C. 360ff) (the FD&C Act). Under this statutory section, a sponsor who receives an approval for a drug or biological product to treat or prevent a rare pediatric disease (as defined by statute) may, if the statute's criteria are met, qualify for a voucher which can be used to receive a priority review for a subsequent marketing application for a different product. The draft guidance is intended to assist developers of rare pediatric disease products in assessing whether their product may be eligible for rare pediatric disease designation and a rare pediatric disease priority review voucher. It also clarifies the process for requesting such designations and vouchers, sponsor responsibilities upon approval of a rare pediatric disease product application, and the parameters for using and transferring a rare pediatric disease priority review voucher.

The draft guidance provides FDA's interpretation of a variety of terms in the statute. It defines ''rare pediatric disease'' as a disease or condition with an entire prevalence of less than 200,000 in the United States and with more than 50 percent of patients living with the disease aged 0 through 18 years. It provides sponsors information on how to calculate and document prevalence in their requests for designation. It explains that, in order for an application to qualify for a rare pediatric disease priority review voucher, it must meet several statutory requirements, including being for a human drug that contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any other application under section 505(b)(1), 505(b)(2), or 505(j) of the FD&C Act (21 U.S.C. 355(b)(1), 355(b)(2), or 355(j)) or section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 42 U.S.C. 262(k).

The draft guidance also outlines for sponsors the procedures for requesting rare pediatric disease designation and rare pediatric disease priority review vouchers and describes the information to include in the designation request and the voucher request. Additionally, it describes how FDA will respond to requests for rare pediatric disease designation and vouchers.

Finally, the draft guidance describes the processes by which a rare pediatric disease priority review voucher is to be awarded, used, and transferred to another sponsor. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on Rare Pediatric Disease Priority Review Vouchers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Rare Pediatric Disease Priority Review Vouchers, Draft Guidance for Industry.

Description of Respondents: Respondents to this collection of information are sponsors that develop drugs and biological products.

Burden Estimate: This draft guidance on Rare Pediatric Disease Priority Review Vouchers is intended to assist developers of rare pediatric disease products in assessing whether their product may be eligible for rare pediatric disease designation and a rare pediatric disease priority review voucher.

The draft guidance clarifies the process for requesting such designations and vouchers, sponsor responsibilities upon approval of a rare pediatric disease product application, and the parameters for using and transferring a rare pediatric disease priority review voucher.

FDA has OMB approval under the PRA for the submission of new drug applications (NDAs) and related submissions under 21 CFR part 314 (OMB control number 0910–0001), biologics license applications (BLAs) and related submissions under 21 CFR part 601 (OMB control number 0910–0338), and orphan-drug designation requests and related submissions under 21 CFR part 316 (OMB control number 0910–0167). The draft guidance describes five collections of information that are not currently approved by OMB under the PRA: (1) The request for a rare pediatric disease designation, (2) the request for a rare pediatric disease priority review voucher, (3) the notification of intent to use a voucher, (4) the notification to transfer a voucher, and (5) the post-approval report.

These collections of information will be used by the Agency to issue rare pediatric disease designations and vouchers, prepare for an incoming priority review, and maintain awareness

about which sponsors currently hold vouchers.

A. Request for Rare Pediatric Disease Designation

Under the draft guidance, a stakeholder interested in obtaining a rare pediatric disease designation should include information about the drug product and its proposed mechanism of action, a description of the rare pediatric disease for which the drug is being or will be investigated, and documentation that the disease or condition for which the drug is proposed is a ''rare pediatric disease'' as defined in section 529(a)(3) of the FD&C Act.

FDA estimates that annually a total of approximately 30 respondents will complete one rare pediatric disease designation request as described in question 8 of the draft guidance. FDA estimates that preparing these designation requests will take approximately 75 hours for each designation request. This includes the time that may be needed to respond to FDA actions and requests.

B. Request for Rare Pediatric Disease Priority Review Voucher

As described more fully in the draft guidance, the information to be provided in a request for a priority review voucher will depend on whether the sponsor has previously received rare pediatric disease designation. Sponsors who have received rare pediatric disease designation will include the designation letter with the voucher request explaining how the application meets all of the remaining eligibility criteria. Sponsors who have not requested rare pediatric disease designation should include in a voucher request prevalence estimates as of the time of NDA/BLA submission, with supporting documentation, and explain how the application meets all of the remaining eligibility criteria.

We estimate that annually a total of approximately 20 respondents will complete one rare pediatric disease priority review voucher request as described in response to question 14 of the draft guidance. We estimate that preparing these designation requests will take approximately 40 hours for each rare pediatric disease priority review voucher request. This includes the time that may be needed to respond to FDA actions and requests.

C. Notification of Intent To Use Voucher

The sponsor redeeming a rare pediatric disease voucher must notify FDA of its intent to submit an application with a priority review voucher at least 90 days before submission of the application, and must include the date the sponsor intends to submit the application.

FDA estimates that annually a total of approximately 3 respondents will complete one Notification of Intent to Use a Voucher as described in response to question 18 of the draft guidance. We estimate that preparing each of these Notifications of Intent to Use a Voucher will take approximately 8 hours.

D. Transfer Notification

Each person to whom a voucher is transferred must notify FDA of the change of voucher ownership within 30 days after the transfer. This notification should include a letter from the previous owner to the current owner and a letter from the current owner to the previous owner, each acknowledging the transfer. Any sponsor redeeming a voucher should include these transfer letters in the application submitted to FDA. A complete record of transfer must be made available to FDA to redeem a transferred voucher.

FDA estimates that annually a total of approximately 2 respondents will complete Transfer Notifications as described in response to question 20 of the draft guidance. We estimate that preparing each of these Transfer Notifications will take approximately 8 hours.

E. Post-Approval Report

The sponsor of an approved rare pediatric disease product application must submit a report to FDA no later than 5 years after approval that addresses the following, for each of the first four post-approval years: (1) The estimated population in the United States with the rare pediatric disease for which the product was approved (both the entire population and the population aged 0 through 18 years); (2) The estimated demand in the United States for the product; and (3) the actual amount of product distributed in the United States.

FDA estimates that annually a total of approximately 2 respondents will complete post-approval reports, as described in response to question 6 of the draft guidance. We estimate that each of these post-approval reports will take about 20 hours to complete.

The total estimated annual reporting burdens for the draft guidance are as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Description of burden	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rare pediatric disease designation request	30	1	30	75	2,250
Rare pediatric disease priority review voucher request	20	1	20	40	800
Notification of intent to use a voucher	3	1	3	8	24
Transfer notification	2	1	2	8	16
Post-approval report	2	1	2	20	40
Total burden hours					3,130

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

Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, Rm. 5295, 10903 New Hampshire Ave., Silver Spring, MD 20993.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm*, or *http://www.regulations.gov.*

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27022 Filed 11–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1285]

Smith Miller and Patch, Inc. et al.; Withdrawal of Approval of 14 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 14 new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: November 17, 2014.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of November 6, 2013 (78 FR 66748), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 14 NDAs because the firms had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the 14 applications listed in table 1 of this document.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	Applicant
NDA 004979	Multi-Vitamin Tablets	Smith Miller and Patch Inc., P.O. Box 367, San German, PR 00753.
NDA 008176	Methostan (methandriol) Tablets	Do.
NDA 008326	Methischol (inositol/vitamin B12/racemethionine/choline chloride) Injection.	USV Pharmaceutical Corp., 500 Virginia Dr., Fort Washington, PA 19034–2779.
NDA 008362	Corticotropin Injection	Vitarine Pharmaceuticals Inc., 227–15 North Conduit Ave., Springfield Gardens, NY 11413.
NDA 009346	ACTH (corticotropin) Injection	Parke-Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
NDA 009515	Hyrye (riboflavin 5′-phosphate sodium) Injection	S.F. Durst and Co., Inc., 5317–21 North Third St., Philadelphia, PA 19120.
NDA 010415	Flamotide (riboflavin 5′-phosphate sodium) Injection	Philadelphia Ampoule Laboratories, 400 Green St., Philadelphia, PA 19123.
NDA 010565	Duracton (corticotropin) Injection	Nordic Biochemicals Inc., 45 Bay State Rd., Boston, MA 02215.
NDA 010791	Rubivite (cyanocobalamin) Injection	Bel Mar Laboratories, Inc., 6–10 Nassau Ave., Inwood, NY 11696.
NDA 010831	Corticotropin Injection	Organics/LaGrange, Inc., 1935 Techny Rd., suite 14, Northbrook, IL 60062.
NDA 011015	RU–B–12–1000 (cyanocobalamin) Injection	Dow Pharmaceutical Corp., 9550 North Zionsville Rd., Indianapolis, IN 46268.
NDA 011578	Efacin (niacin) Tablet	Person and Covey, Inc., 616 Allen Ave., Glendale, CA 91201.
NDA 017861	Acthar Gel Synthetic (seractide acetate) Injection	Armour Pharmaceutical Co., P.O. Box 511, Kankakee, IL 60901.
NDA 018087	Thyrel TRH (protirelin) Injection	Ferring Pharmaceuticals, Inc., 400 Rella Blvd., suite 300, Suffern, NY 10901.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective November 17, 2014.