

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2017–D–1956 for “Identifying Trading Partners Under the Drug Supply Chain Security Act; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Melissa Mannion, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Identifying Trading Partners Under the Drug Supply Chain Security Act.” The DSCSA (Title II of Pub. L. 113–54) establishes new requirements to develop and enhance drug distribution security by 2023. It does this, in part, by defining different types of entities in the drug supply chain as *trading partners* (i.e., manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers). Among other things, the DSCSA requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers must meet the applicable requirements for being “authorized trading partners.” In addition, the DSCSA outlines requirements for specific trading partners, including drug product tracing and licensure requirements. FDA has received questions about which types of entities are included in each of the trading partner definitions and this guidance is intended to help clarify and explain the relevant statutory provisions. The guidance covers who is considered to be a manufacturer, a repackager, a wholesale drug distributor, a third-party logistics provider, and a dispenser for purposes of certain DSCSA requirements.

##### **II. Additional Issues for Consideration: Specific Request for Comments and Information**

In addition to comments on the draft guidance generally, FDA is requesting comments specifically related to the activities of private-label distributors (PLDs), and whether those activities fall within the definitions under DSCSA of the various trading partners. FDA considers a PLD to be an entity that owns and distributes a manufactured product under its own label or trade name. Because there are many different business models for PLDs, resulting in situations where a PLD could be considered a manufacturer, wholesale distributor, or dispenser, we are asking for comments on how the different business models might impact a PLD’s status as an authorized trading partner under the DSCSA.

This draft guidance is being issued consistent with FDA’s good guidance practices (see 21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Identifying Trading Partners under the Drug Supply Chain Security Act.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: August 18, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–17919 Filed 8–21–17; 11:15 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **Notice of Supplemental Awards to the Territorial Health Departments of Puerto Rico, American Samoa, and U.S. Virgin Islands for the Zika Maternal and Child Health Services Program**

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of Supplemental Award.

**SUMMARY:** HRSA announces the award of supplemental grants under the Zika Response and Preparedness Act to the territorial health departments of Puerto Rico, American Samoa, and U.S. Virgin Islands to address the unmet needs of women, children, and families who are or may be affected by Zika virus (ZIKV) infection.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient of the Award:* Territorial health departments of Puerto Rico, American Samoa, and U.S. Virgin Islands.

*Amount of Non-Competitive Awards:* Approximately \$1,050,000.

*CFDA Number:* 93.110.

*Authority:* Zika Response and Preparedness Act (Pub. L. 114–223) and Section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)).

*Justification:* The current spread of ZIKV poses a significant threat to public health, including the health of women, children, and families who are affected by ZIKV infection. ZIKV infection during pregnancy can cause serious birth defects, especially affecting the neurological system of the infant.

Funding for these awards is available under the Zika Response and

Preparedness Act through Special Projects of Regional and National Significance (SPRANS) funds.

The needs of infants and children affected by ZIKV are complex. Families, health care providers, and public health professionals will be required to work together to assure that community-based, comprehensive, high quality health and social services are available to these children. The support system must address the medical needs of these children, such as regularly screening children who may not be symptomatic at birth; coordinate care through a medical home; finance care needed by children and families; link to community-based services; partner with families; and eventually address transition to adult services. Following HRSA’s December 2016 grant awards to the territorial health departments of Puerto Rico, American Samoa, and U.S. Virgin Islands, recipients continued to identify pregnant women and infants with lab evidence of ZIKV infection that led them to refine their response to ZIKV. HRSA’s Maternal and Child Health Bureau (MCHB) received information from the territorial health departments of unmet needs in their response to ZIKV through monitoring

site visits, regular communication, and prior approval requests. Needs identified by recipients included additional equipment, personnel, and transportation services. With further analysis of other federal funding and the current epidemiologic data, MCHB confirmed additional funding is essential to ensure access to services and a comprehensive medical home for women, children, and families who are or may be affected by ZIKV infection. Disease burden and the significant increase in pregnant women and children with lab evidence of ZIKV infection in American Samoa and the U.S. Virgin Islands was also considered as a factor in determining the allocation of funds to the territories to address unmet needs. The period of performance of the supplemental award will be September 2017 through December 2019.

**FOR FURTHER INFORMATION CONTACT:**

Maria Paz Carlos, Division of State and Community Health, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18N104A, Rockville, Maryland 20857; *MCarlos@hrsa.gov*.

Grantee/organization name	Territory	FY 2017 supplemental awards
Puerto Rico Health Department .....	Puerto Rico .....	\$52,850
American Samoa Health Department .....	American Samoa .....	423,142
U.S. Virgin Islands Health Department .....	U.S. Virgin Islands .....	574,008

Dated: August 18, 2017.

**George Sigounas,**  
*Administrator.*

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**BILLING CODE 4165–15–P**

**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: Federal Tort Claims Act (FTCA) Program Deeming Applications for Health Center Volunteer Health Professionals, OMB No. 0906–XXXX, New**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than September 25, 2017.

**ADDRESSES:** Submit your comments, including the ICR 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 the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Federal Tort Claims Act (FTCA) Program Deeming Applications for Health Center Volunteer Health Professionals OMB No. 0906–XXXX—New.

*Abstract:* Section 224(q) of the Public Health Service (PHS) Act (42 U.S.C. 233(q)), as amended, authorizes the “deeming” of certain individuals as PHS employees for the purposes of receiving Federal Tort Claims Act (FTCA) coverage. Section 224(q) relates to volunteer health professionals (VHPs) of Health Center Program grantees that have been deemed as PHS employees. The Health Center FTCA Program is administered by HRSA’s Bureau of Primary Health Care (BPHC). Sponsoring health centers are required