

TABLE 1—STATUS OF DRAFT GUIDANCE Q&AS AND FINAL GUIDANCE Q&AS—Continued

Q&A category	Q&A Nos.	Previous guidance location	Current guidance location
Part II. Provisions Related to Requirements to Submit a Biologics License Application (BLA) for a “Biological Product”.	Q.I.2 .....	Final .....	Final.
	Q.I.3 .....	Final .....	Final.
	Q.I.4 .....	Final .....	Final.
	Q.I.5 .....	Final .....	Final.
	Q.I.6 .....	Final .....	Final.
	Q.I.7 .....	Final .....	Final.
	Q.I.8 .....	Final .....	Final.
	Q.I.9 .....	Draft .....	Final.
	Q.I.10 .....	Draft .....	Final.
	Q.I.11 .....	Final .....	Withdrawn.
	Q.I.12 .....	Final .....	Draft.
	Q.I.13 .....	Draft .....	Final.
	Q.I.14 .....	Draft .....	Final.
	Q.I.15 .....	Final .....	Final.
	Q.I.16 .....	Draft .....	Draft.
	Q.I.17 .....	Draft .....	Final.
	Q.I.18 .....	Draft .....	Final.
	Q.I.19 .....	Draft .....	Final.
	Q.I.20 .....		Draft.
	Q.I.21 .....		Draft.
	Q.I.22 .....		Draft.
	Q.I.23 .....		Draft.
	Q.I.24 .....		Draft.
	Part III. Exclusivity .....	Q.II.1 .....	Final .....
Q.II.2 .....		Final .....	Final.
Q.II.3 .....		Draft .....	Final.
	Q.III.1 .....	Draft .....	Final.
	Q.III.2 .....	Final .....	Final.

This guidance finalizes certain Q&As that were included in the draft guidance issued on May 13, 2015. FDA considered written comments the Agency received regarding these Q&As, and made changes to the Q&As, as appropriate. Editorial changes were made primarily for clarification.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Questions and Answers on Biosimilar Development and the BPCI 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. This guidance is not subject to Executive Order 12866.

FDA is announcing, in a separate document published elsewhere in this issue of the **Federal Register**, the availability of the draft guidance for industry entitled “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).”

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314.50 for submission of a new drug application have been approved under OMB control number 0910–0001. The collections of information in section 351(a) of the PHS Act under part 601 (21 CFR part 601) for submission of a BLA have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act under part 601 for submission of a BLA have been approved under OMB control number 0910–0719. The collections of information for submission of a meeting package to the appropriate review division with the meeting request as described in the draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products” have been approved under OMB control number 0910–0802.

**III. Electronic Access**

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/Drugs/Guidance>

*ComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.*

Dated: December 6, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–26853 Filed 12–11–18; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR–7007–N–06]

**60-Day Notice of Proposed Information Collection: Data Collection for EnVision Center Demonstration Sites**

**AGENCY:** Office of Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** The Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information.

The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* February 11, 2019.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410-5000; telephone 202-402-5534 (this is not a toll-free number) or by email at [Anna.P.Guido@hud.gov](mailto:Anna.P.Guido@hud.gov) for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

**FOR FURTHER INFORMATION CONTACT:** Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410-5000; email Anna P. Guido at [Anna.P.Guido@hud.gov](mailto:Anna.P.Guido@hud.gov) or telephone 202-402-5535 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the proposed collection of information described in Section A.

#### A. Overview of Information Collection

*Title of Information Collection:* HUD EnVision Centers Demonstration Data Collection.

*OMB Approval Number:* Pending.

*Type of Request:* New.

*Form Number:* TBD.

*Description of the need for the information and proposed use:* HUD seeks to collect data from the EnVision Center Demonstration sites to find out the effectiveness of collaborative efforts by government, industry, and nonprofit organizations to accelerate economic mobility of low-income households in communities that include HUD-assisted housing. The demonstration builds upon existing partnerships and continues collaborative work to improve the lives of residents housed with HUD assistance, by providing a forum by which cross-sector organizations can come together to design and implement local interventions to advance self-sufficiency and economic mobility through a four-pillar approach to

opportunity. The four pillars are: (1) Economic Empowerment, (2) Educational Advancement, (3) Health and Wellness, and (4) Character and Leadership. HUD believes that these four pillars can be the foundation for driving collaboration amongst communities, the private sector, and the federal government, intended to improve the quality of life of HUD-assisted and low-income households and to empower them to become self-sufficient.

Located in or near Public Housing Authorities (PHA), EnVision Centers are centralized hubs for supportive services focused on the four pillars listed above. The EnVision Centers demonstration is premised on the notion that financial support alone is insufficient to solve the problem of poverty. Intentional and collective efforts across a diverse set of organizations with an even more diverse set of supportive services expertise are needed to implement a holistic approach to long-lasting self-sufficiency. Envision Centers embody this concept, bringing together a diverse set of organizations and resources under one roof, alleviating barriers commonly faced by residents and other low-income individuals including access and transportation. An example of this includes the IRS offering free tax preparation services to residents in the EnVision Center, while simultaneously having the Department of Education provide coordinators to aide residents in gathering key tax and other pertinent information needed to apply for the Free Application for Federal Student Aid (FAFSA). Another example includes; CyberPatriots offering computer technical classes through Cybergenerations while the Small Business Administration (SBA) provides "off the shelf" entrepreneurship courses to educate residents, and other low-income individuals interested in launching their own businesses.

In its report released in January 2011, that focused on Temporary Assistance for Needy Families, Employment Services and Workforce Investment Act Adult employment programs funded by the U.S. Departments of Labor, Education, and Health and Human Services, the Government Accountability Office (GAO) found that efficiencies in offering government services could be achieved by co-locating services and consolidating administrative structures. EnVision Centers aim to help foster efficiencies through co-locating government services and consolidating administrative structures. Data collection is necessary to assess and determine eligibility for EnVision Center designation and

identify other activities to be conducted at EnVision Centers.

Potential EnVision Center sites are required to submit letters of commitment and Action Plans that promote and expand economic mobility. These Action Plans will describe the goals of the community's participation in the demonstration and provide, to the extent as possible, objective goals regarding the number of partnerships established with state and local government, non-profits, faith-based organizations, and private and philanthropic organizations. Once designated as an EnVision Center, designees are required to keep records (e.g., Action Plans, etc.) that document how the Demonstration is being implemented, cooperate with the evaluation, and commit to providing quarterly progress reports. The Action plan serves as a vehicle for bringing together stakeholders and providing them with a tangible path for achieving the goals of the EnVision Center. These plans will specify and formalize the participation of community stakeholders, describe gaps in current service delivery models, describe the onsite arrangements for intake processing and referrals to network stakeholders, identify the physical location(s) which can act as a shared services site to house the EnVision Center, and/or outline specific benchmarks and goals for the EnVision Center. These plans could also capture the goals of the community's participation in the demonstration and provide, to the extent possible, objective indicators of success regarding the number of partnerships established with state and local government, non-profits, faith-based organizations, and private and philanthropic organizations. Progress reports will be required on a quarterly basis in order to track EnVision Center implementation, assess and address Technical Assistance (TA) needs, and monitor activities, outputs and outcomes. A Customer Satisfaction survey will be administered within 30-days to individuals who go through the EnVision Center's intake process. This will provide information about how participants are experiencing the supports, referrals, and placement processes.

Envision Center sponsors may include Public Housing Authorities (PHAs), state and local governments, Tribes, Tribally-Designated Housing Agencies, participating jurisdictions, housing counseling agencies, multifamily owners/operators, faith-based and nonprofit organizations, and Continuums of Care (CoC).

Respondents (i.e., affected public):  
Executive Sponsor, Center Coordinator,  
Navigator and Participants.

Respondent	Occupation	SOC code	Median hourly wage rate
EnVision Center Executive Sponsor .....	Chief Executive .....	11-1011	\$88.11
EnVision Center Director .....	General and Operations Managers .....	11-1021	48.27
EnVision Center Navigator .....	Social and Human Service Assistant .....	21-1093	15.92
EnVision Center Participant .....	Federal Minimum Wage Rate .....	N/A	7.25

Source: Bureau of Labor Statistics, Occupational Employment Statistics (May 2017), [https://www.bls.gov/oes/current/oes\\_stru.htm](https://www.bls.gov/oes/current/oes_stru.htm) and Department of Labor, Minimum Wage (2009), <https://www.dol.gov/general/topic/wages/minimumwage>.

The EnVision Center Executive Sponsor and Envision Center Director at the 200 EnVision Centers will complete the Commitment Letter. The EnVision Center Executive Sponsor, EnVision Center Director and the EnVision Center Navigator will complete the Action Plan and the Quarterly Report while the EnVision Center Participant will

complete the Customer Satisfaction Survey.

For the Commitment Letter, it is assumed that the EnVision Center Executive Sponsor and the EnVision Center Director will need 0.25 hours to complete this a year. The total number of respondents would be 200 based on the 200 centers.

For the Action Plan, it is assumed that the EnVision Center Executive Sponsor and EnVision Center Director will need one hour to complete this and the EnVision Center Navigator will need seven hours to complete this for an average of 8 hours total.

For the Quarterly Reports, it is assumed that the EnVision Center Executive Sponsor and EnVision Center Director will need one hour to complete the review and and the EnVision Center Navigator will need five hours to complete this task for an average of 6 hours total.

For the Customer Satisfaction Survey, we anticipate an average 200 Envision Center Participant visits a year from each of the 200 centers. This is a total of 40,000 respondents per year with each survey having a completion time of three minutes.

Information collection	Number of respondents	Response frequency	Burden hours per response	Annual burden hours	Hourly cost per response	Total cost
Commitment Letter (Completed by the EnVision Center Navigator/EnVision Center Executive Sponsor/EnVision Center Director) .....	200	1	0.25	50.00	\$68.19	\$3,409.50
Action Plan (Completed by the EnVision Center Navigator/EnVision Center Executive Sponsor/EnVision Center Director) .....	200	1	8.00	1,600.00	22.45	35,920
Quarterly Report (Completed by the EnVision Center Navigator/EnVision Center Executive Sponsor/EnVision Center Director) .....	200	4	6.00	4,800.00	24.63	118,224
Customer Satisfaction Survey (Completed by the EnVision Center Participant) .....	40,000	1	0.05	2,000.00	7.25	14,500.00
Total .....	40,600	.....	.....	8450.00	.....	172,053.50

**B. Solicitation of Public Comment**

This notice solicits comments from members of the public and affected parties concerning the collection of information described in Section A on the following: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 of information

on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 30, 2018.

**Todd M. Richardson,**  
General Deputy Assistant, Secretary for Policy Development and Research.

[FR Doc. 2018-26902 Filed 12-11-18; 8:45 am]

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**INTERNATIONAL TRADE COMMISSION**

[Investigation No. 731-TA-739 (Fourth Review)]

**Clad Steel Plate From Japan**

**Determination**

On the basis of the record <sup>1</sup> developed in the subject five-year review, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the

<sup>1</sup> The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).