UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0840
Voluntary Qualified Importer Program; Guidance for Industry

Request for Non-Substantive/Non-Material Change:

The Food and Drug Administration (FDA or we) is submitting this nonmaterial/non-substantive change request (83-C) to include an updated version of the Voluntary Qualified Importer Program (VQIP) guidance.

We are making changes to the guidance to provide clarity regarding a VQIP inspection, add flexibility to allow VQIP participants to add new foreign suppliers and foods to their existing VQIP program throughout the year, and extend the deadline to submit the notice of intent to participate in the program and the application to September 1 (currently the deadline is May 31).

- The first change makes VQIP inspections optional and utilizes existing operational pathways, relying on application review as the main component for approving an importer that has a recent Foreign Supplier Verification Program (FSVP) or Hazard Analysis and Critical Control Points (HACCP) inspection with acceptable results. This adjustment would not impact the information collected from participants but would enhance program efficiency and enable FDA to adjust inspection-related costs in the user fee calculation.

- The second change allows participants to add new foreign suppliers and foods to their existing program throughout the year. This change aims to provide greater flexibility to participants by allowing additional time to complete the process of obtaining and scheduling audits from accredited certification bodies under FDA's Accredited Third-Party Certification Program (also referred to as the third-party program or TPP) to receive the appropriate facility certification. The VQIP portal currently allows participants to add food from a foreign supplier already in an application throughout the year and therefore adding this flexibility does not require updates to the User Guide. We do not anticipate that there will be an influx of amendments because of this change and do not foresee an increase in burden estimate.

- The third change extends the deadline for submitting the notice of intent to participate and the application to September 1st (currently May 31st). This extension provides participants with more time to obtain facility certificates and submit their applications. This change does not require any additional information from the participants.

We are also making minor changes for clarity and consistency within the guidance and between FDA's related foods programs (VQIP and TPP), such as:

- Including cross-references to other sections of the guidance,
- Adding regulatory definitions within footnotes,
- Using the term "criteria" consistently throughout, and

- Aligning language in the VQIP guidance with that used in the draft guidance for industry "Questions and Answers on the Accredited Third-Party Certification Program" (TPP guidance) which can be accessed at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-accredited-third-party-certification-program.

FDA's TPP is established and administered under section 808 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d) and codified in 21 CFR part 1, subpart M (21 CFR section 1.600 through 1.725). The collections related to the TPP regulation and guidance are approved under OMB Control No. 0910-0750. One of the criteria for participation in VQIP is to have a current facility certification issued in accordance with FDA's TPP for each foreign supplier of food offered for import under VQIP, therefore it is helpful for participants if language used by the programs is aligned. The TPP guidance issued in April 2022 and used specific terms and included additional explanations of FDA product codes normally transmitted during the import process. For consistency, we are updating terms and references related to TPP and are also including additional explanation of FDA product codes in this updated ed VQIP guidance to ensure the information provided matches other elements reviewed by FDA.

We believe these changes are necessary to give current and future program participants flexibility and more accurate information. At this time, we believe the current estimate of 24 respondents and 1,936 hours annually for activities discussed in the guidance already accounts for changes to the number of respondents and responses that may result from these guidance updates. We have therefore made no adjustment to the currently approved burden estimate in control no. 0910-0840.

We are providing both redline and clean copies of the guidance to facilitate review and highlight changes.


Guidance-VoluntaryQualifiedImporterProgr


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Submitted: July 2024