Date: September 14, 2020

To: Julie Wise, Office of Management and Budget

From: Ellen J. Flannery, Deputy Center Director for Policy, Center for Devices and Radiological Health, U.S. Food and Drug Administration

SUBJECT: Request for Emergency Clearance of the Paperwork Reduction Act Package for the Revision of OMB Control No. 0910-0498 to Add Certification for Devices not Exported from the United States

Request for Emergency Clearance

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020. Section 3856 of the CARES Act contained a provision that made the U.S. Food and Drug Administration (FDA) immediately obligated to review and process requests for certifications for devices not exported from the United States. These new certificates will be issued for products that have received FDA marketing authorization, are exempt from 510(k) or are preamendment, and will be shipped from one foreign country to another without entering U.S. commerce. The Food, Drug, and Cosmetic (FD&C) Act anticipates that FDA will issue certifications within 20 days of the establishment's request for such documentation, and that FDA will collect fees for such certifications, as set forth in section 801(e)(4) of the FD&C Act.

FDA's Center for Devices and Radiological Health (CDRH) is requesting use of the emergency clearance process under 44 USC 3507(j) and 5 CFR 1320.13 for the revision of OMB Control No. 0910-0498 to add the collection of information required to issue certain new certificates. Pursuant to 5 CFR 1320.13(a)(1) and (2)(iii), (b), and (c) as set forth more fully below, I have determined that:

(1) The revision of the collection of information is needed prior to the expiration of normal clearance time periods and is essential to the mission of the FDA; and

(2) FDA cannot reasonably comply with normal clearance procedures because use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed and to prevent or disrupt the required collection of information; and

(3) FDA is requesting that OMB allow use of its emergency clearance process to immediately approve the revision of OMB Control No. 0910-0498, so that FDA may immediately collect the information necessary to issue CDNEs; and

(4) FDA has interacted with interested members of the public and has taken steps to create forms and processes that will minimize the burden of the collection of information.

Background:

Customers of Domestic Device Exporters May Request Certificates to a Foreign Government: Section 801(e)(4) enables establishments exporting FDA-regulated devices from the United States to request that FDA provide a certificate to a foreign government (CFG) containing information about the exported product's regulatory or marketing status. In some circumstances, reviewing a CFG is a required part of the process to register or import a product into another country.
Establishments exporting from the U.S. that request a CFG (OMB Control No. 0910-0498) provide FDA with several categories of information, including the requester's name, address, and registration number; a list of all manufacturers involved in the manufacturing process, specification developers, repackagers/relabelers, remanufacturers, reprocessors, foreign exporters, contract manufacturers, and contract sterilizers; a product list; the product code; product class; marketing status; a list of any recalls within the past 10 years; and a list of any enforcement actions against the product. In addition, CFG requesters represent that the products meet certain marketing requirements.[1]

Section 801(e)(4)(A) and (B) of the FD&C Act authorize FDA to collect a fee of up to $175 per request, where FDA issues such a request within 20 days.

FDA reviews the information the requester provides to determine whether the product that is the subject of the request qualifies for a CFG. FDA does not issue CFGs if the product is not in compliance with applicable provisions of the FD&C Act, if FDA has initiated an enforcement action, or if the requesting facility is not registered with FDA.

The CARES Act Provided for Certification to Foreign Customers of Foreign Establishments: On March 27, 2020, the CARES Act was signed into law. Section 3856(a) of the CARES Act made a technical correction, which amended section 801(e)(4)(E)(iii) of the FD&C Act to provide that, under "paragraph" (4) of section 801(e), any registered device establishment can request a certification, ***whether the establishment is located inside or outside of the United States, and regardless of whether such products are to be exported from the United States***. The CARES Act was effective on March 27, 2020, and Congress did not provide either a different effective date or implementation period for the change to section 801(e)(4)(E)(iii), and did not address section 801(e)(4)(E)(iii)'s 20 day statutory deadline.

By amending section 801(e)(4)(E)(iii) of the FD&C Act, the CARES Act[2] gave FDA new authority and required FDA to issue certifications for foreign devices that move between foreign countries without entering the United States. To implement this new authority, FDA has created

[1] Section 801(e)(4)(A) of the FD&C Act authorizes FDA to issue a CFG for devices (a) that may be legally marketed in the United States because they meet the applicable requirements of the Act, or (b) that may not be legally marketed under the Act although they meet the requirements of 801(e) or 802, and thus may be legally exported. In their CFG documentation, requesters represent that the device meets these requirements.

[2] SEC. 3856. TECHNICAL CORRECTIONS.
(a) IMPORTS AND EXPORTS.— Section 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking ''subparagraph'' each place such term appears and inserting ''paragraph.''

a new form FDA 3613g (attached) for requesters to provide the information necessary to issue the certifications, and FDA anticipates issuing a revised certificate for devices not exported from the United States, or "CDNE."

A CFG certifies that the device has marketing authorization, or that it may be legally exported, and that the device is being exported from the United States. In contrast, a CDNE will certify that FDA is not aware of any applicable requirements of the FD&C Act that would prohibit shipment of this device from one specific foreign country to another. A CDNE does not certify that the requestor has authorization to import or market the device in the United States. Because the CFG does not address devices that are shipped from one foreign country to another without entering U.S. interstate commerce, to evaluate CDNE requests, FDA must collect slightly different (albeit less) information than the CFG collection, as FDA issues a CDNE to requesters for foreign-to-foreign trade, and not U.S.-to-foreign transactions.

Stakeholders have inquired about how to request CDNEs, and CDRH has developed form FDA 3613g in anticipation of facilitating their information collections. At least 25,360 foreign establishments are registered with FDA. To date, at least one trade organization representing over 400 registered establishments has inquired about when and how CDRH will begin to issue the foreign certifications authorized by the CARES Act. In addition, FDA has received at least 10 phone calls and emails seeking information regarding FDA's foreign certification process. Based on industry's significant interest in the subject, FDA anticipates that many more foreign establishments may request foreign-to-foreign certification. CDRH needs to be able to respond to a large number of interested stakeholders, some of whom have already reached out to CDRH -- to provide advice, forms, processes, and methods to obtain these certifications..

Need for Emergency Clearance:

As described below, in the absence of emergency processing and immediate approval of the information collection, FDA will be unable to comply with sections 801(e)(4)(A) and (B) of the FD&C Act. Standard clearance timelines would prevent FDA from processing requests from foreign customers who desire information about the device's U.S. regulatory or marketing status, in the manner recently mandated by Congress under the CARES Act. Without emergency clearance – and the instructions and forms that FDA will provide to interested stakeholders -- the absence of PRA authorization would disrupt the collection of information necessary to issue CDNEs.

FDA Needs Emergency Clearance to Comply with Other Aspects of Section 801(e)(4)(A) and (B): Section 801(e)(4)(A) and (B) also anticipates that FDA will collect fees for certifications if it is able to issue certifications within 20 days of the receipt of a request. FDA has already received multiple inquiries and requests, and FDA anticipates that additional firms will also request CDNEs, which will provide FDA the ability to take advantage of the fee provisions contemplated by section 801(e)(4). Without expedited PRA approval, FDA will not be able to issue certificates within 20 days of the request, and FDA will be unable to collect the fees to which it is entitled.

FDA Needs Emergency Clearance to Prevent Disrupting the Information Collection Required by CARES and Section 801(e)(4)(A) and (B):

In addition, without emergency clearance and the accompanying form FDA 3613g, FDA will be unable to ensure that interested stakeholders will provide complete requests, which include the information necessary to issue CDNEs. Furthermore, without the ability to receive information from industry in a standardized format, FDA will be unable to process requests within the timeline contemplated by section 801(e)(4).

To qualify for a CDNE, the requesting establishment must submit only that information necessary to certify that the facility that appears on the certificate is registered; that the device is authorized for marketing in the United States, is exempt from 510(k), or is preamendment; that the facility has been inspected or audited (with the audit findings supplied to FDA) within the past three years; and that the requester does not intend to export the device that is the subject of the CDNE from the United States. FDA has developed form FDA 3613g to be submitted through the CDRH Export Certification Application and Tracking System (CECATS) to submit this standardized collection, which will lessen both industry and FDA's burden. For example, form FDA 3613g asks applicants to certify (and, in some cases, provide information) demonstrating that the facility is registered, that the device is authorized for marketing in the United States (or is 510(k) exempt or preamendment), that the facility has been inspected or audited (with the audit findings supplied to FDA), and that the requester does not intend to export the device from the United States.

The information collected through the form submitted in CECATS is necessary to reduce the processing time for certificates to less than the 20 days as required by the FD&C Act. Without the requested information, FDA staff would need to search several databases covering many years of registration and inspectional data. With the requested information, staff can focus immediately its data search to confirm the information provided. Utilizing the form submitted in CECATS will ensure that all information necessary to show that the device(s) meet the conditions of the CARES Act is included in the request, so that the request will be adequate to enable FDA to respond in a timely manner.

Accordingly, FDA is requesting that OMB allow use of its emergency clearance process to immediately approve the revision of OMB Control No. 0910-0498, so that FDA may immediately collect the information necessary to issue CDNEs.