

product information, particularly for applications that include multiple products.

All information is entered using electronic Forms FDA 3613d, 3613e, and 3613k and used to evaluate certificate requests. The eCATS Module is Form FDA 3613k, where Form FDA 3613e is the Certificate of Free Sale (<https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>). All “forms” are electronic and part of the eCATS or CAP portal accessed via <https://www.access.fda.gov>. To view representations of the forms, you have to download the instructions, which are accessible from the following links: <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

While burden associated with information collection activities for

export certificates issued for other FDA-regulated products is approved under OMB control number 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (CFSANExportCertification@fda.hhs.gov) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at <https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics> and instructions for requesting export certificates for food (Forms FDA 3613e and 3613k) are available online at <https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food>.

Description of Respondents: The respondents to this collection of information are firms interested in

exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

In the **Federal Register** of March 16, 2021 (86 FR 14452), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment offering general support for our cosmetic export certificate program. The comment also recommended FDA consider providing certificates that allow exporters to use an exemption from requirements in China for animal testing for certain imported cosmetic products. We appreciate the comment and continue to seek ways to increase the utility of the information collection as our limited resources permit. At the same time, the comment did not suggest we revise the burden we attribute to the associated information collection activity.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent	Form No. ²	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	FDA 3613d	113	3	339	0.5 (30 minutes)	170
Food	FDA 3613e, 3613k	468	9	4,212	0.5 (30 minutes)	2,106
Total	2,276

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

² All forms are submitted electronically via FDA Industry Systems.

Based on a review of the information collection since our last OMB approval, we have reduced our burden estimate. The burden estimate has been lowered due to a reduced number of respondents. We base our estimates on our experience with certificate applications received in the past 3 fiscal years.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services (Department or HHS) is announcing the withdrawal of a notice published in the **Federal Register** on January 21, 2021, entitled “Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation.” HHS also withdraws the requests for proposals issued on its website on September 24, 2020, and revised on January 13, 2021, and ends the period for submission of proposals

in response to the requests for proposals.

DATES: The notice published in the **Federal Register** on January 21, 2021, at 86 FR 6343, is withdrawn as of July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993, 301–796–1054.

SUPPLEMENTARY INFORMATION: On September 24, 2020, HHS issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs (collectively, the RFPs) and posted related “Frequently Asked Questions” documents (FAQs) on its website. On January 21, 2021, HHS published a notice in the **Federal Register** entitled “Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation” (the HHS Notice) (86 FR 6343). The HHS Notice referred to revised versions

of the RFPs. The responses to the RFPs were directed in the HHS Notice and in the RFP for Personal Prescription Drug Importation issued on September 24, 2020, and revised on January 13, 2021, to be submitted to an HHS email address: import@hhs.gov, while the RFP for Insulin Reimportation Programs issued on September 24, 2020, and revised on January 13, 2021, directed that responses be sent to import@hhs.gov and to the Director of the FDA Import Division in the region of the intended port of entry. The Department is not aware that any proposals were received in response to the HHS Notice or RFPs. The HHS Notice, RFPs, and FAQs are withdrawn. All website statements and other informal issuances with respect to the HHS Notice and RFPs are also withdrawn. Accordingly, no proposals submitted to HHS or FDA in response to the HHS Notice or RFPs on or after July 9, 2021 will be considered by HHS or FDA. HHS intends to consider alternatives to the RFPs.

Dated: June 11, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: June 28, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021-14637 Filed 7-8-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0025]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 9, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0721. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

OMB Control Number 0910-0721—Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue regulations concerning animal food. Specifically, section 403(i) of the FD&C Act (21 U.S.C. 343(i)) requires that certified color additives used in or on a food

must be declared by their common or usual names and not be designated by the collective term “colorings.” Our regulations in part 501 (21 CFR part 501) set forth the requirements for animal food labeling. Under § 501.22(k)(21 CFR 501.22(k)), animal food manufacturers must declare on the animal food label the presence of certified and noncertified color additives in their animal food products. Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. The purpose of the labeling is to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

In the **Federal Register** of March 4, 2021 (86 FR 12690), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received 22 comments expressing the importance of color additive information on pet food labeling, along with other ingredient disclosures. FDA appreciates these comments; at this time, we are not revising the regulations found at § 501.22(k) related to color additive information on the labeling of animal food.

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Respondents to this collection of information are manufacturers of pet food products that contain color additives.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes)	647

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