

determining this patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZEPZELCA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZEPZELCA is 4,170 days. Of this time, 3,987 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* January 16, 2009. The applicant claims January 14, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 16, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act:* December 16, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for ZEPZELCA (NDA 213702) was initially submitted on December 16, 2019.

3. *The date the application was approved:* June 15, 2020. FDA has verified the applicant's claim that NDA 213702 was approved on June 15, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must

comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26009 Filed 11–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Certificate of Origin (CBP Form 3229)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than January 31, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0016 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: CBP_PRA@cbp.dhs.gov.

Due to COVID–19-related restrictions, CBP has temporarily suspended its

ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, telephone number 202–325–0056, or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP

invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (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, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Certificate of Origin.

OMB Number: 1651–0016.

Form Number: CBP Form 3229.

Current Actions: Extension without change.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: CBP Form 3229, Certificate of Origin, is used by shippers and

importers to declare that goods being imported into the United States are grown or the product of an insular possession of the United States and/or produced or manufactured in a U.S. insular possession from material grown in or product of such possession. This form includes a list of the foreign materials in the goods, including their description and value. CBP Form 3229 is used as documentation for goods entitled to enter the U.S. free of duty. This form is authorized by General Note 3(a)(iv) of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202) and is provided for by 19 CFR part 7.3. CBP Form 3229 is accessible at: <https://www.cbp.gov/newsroom/publications/forms?title=3229&=Apply>.

Type of Information Collection: Certificate of Origin (CBP Form 3229).
Estimated Number of Respondents: 113.

Estimated Number of Annual Responses per Respondent: 20.

Estimated Number of Total Annual Responses: 2,260.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 753.

Dated: November 23, 2021.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, U.S. Customs and Border Protection.

[FR Doc. 2021-25997 Filed 11-29-21; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection [1651-0100]

Petition for Remission or Mitigation of Forfeitures and Penalties Incurred

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than

January 31, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651-0100 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: CBP_PRA@cbp.dhs.gov.

Due to COVID-19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT:

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177, telephone number 202-325-0056, or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (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, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request

for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Petition for Remission or Mitigation of Forfeitures and Penalties Incurred.

OMB Number: 1651-0100.

Form Number: CBP Form 4609.

Current Actions: Extension without change.

Type of Review: Extension (without change).

Affected Public: Individuals and Businesses.

Abstract: CBP Form 4609, *Petition for Remission of Forfeitures and Penalties Incurred*, is completed, and filed with the CBP FP&F Officer designated in the notice of claim by individuals who have been found to be in violation of one or more provisions of the Tariff Act of 1930, or other laws administered by CBP. Persons who violate the Tariff Act of 1930, or other laws administered by CBP, are entitled to file a petition seeking remission or mitigation of a fine, penalty, or forfeiture incurred under these laws. This petition is submitted on CBP Form 4609. The information provided on this form is used by CBP personnel as a basis for granting relief from forfeiture or penalty. CBP Form 4609 is authorized by 19 U.S.C. 1618 and provided for by 19 CFR 171.1. It is accessible at <https://www.cbp.gov/newsroom/publications/forms?title=4609>.

This collection of information applies to members of the public who may not be familiar with import procedures and CBP regulations. It may also be used by the importing and trade community who are familiar with import procedures and with the CBP regulations.

Type of Information Collection: CBP Form 4609.

Estimated Number of Respondents: 1,610.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 1,610.

Estimated Time per Response: 14 minutes.

Estimated Total Annual Burden Hours: 376.

Dated: November 23, 2021.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, U.S. Customs and Border Protection.

[FR Doc. 2021-25998 Filed 11-29-21; 8:45 am]

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