

guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without initially seeking prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2)). We made this determination in light of the significant potential for a public health emergency associated with New World Screwworm, *Cochliomyia hominivorax*, (NWS).

NWS is a parasitic fly that lays eggs in and on open wounds and mucous membranes of warm-blooded animals. NWS can infest livestock, pets, wildlife, occasionally birds, and in rare cases, people. Although eradicated from North America and Central America decades ago, NWS has progressed north since 2022 and is approaching the U.S. border with Mexico. This parasite poses an emerging threat to livestock and food security, with potential impacts on both national security and animal health. In order to respond effectively and efficiently to this threat, FDA must act expeditiously to review and, where appropriate, approve or authorize animal drugs for NWS myiasis.¹ Such approvals may include conditional approvals under section 571 of the FD&C Act for new indications for products that are currently approved for a different indication(s) under section 512 of the FD&C Act.

Section 571(f)(2) of the FD&C Act permits the agency, through regulation or guidance, to determine under what conditions an intended use that is the subject of a conditional approval may be included in the same product label with any intended use approved under section 512 of the FD&C Act, *i.e.*, a full approval. The guidance document refers to this practice as “dual labeling.” While FDA intends to issue guidance in the future to more broadly address conditions under which it would consider dual labeling appropriate, FDA is issuing this guidance concerning products with indications for NWS at this time due to the particular need to act quickly and efficiently to address the imminent health threat of NWS.

Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

The guidance represents the current thinking of FDA on “Dual Labeling for Fully Approved and Conditionally Approved New Animal Drugs With a

New World Screwworm-Related Indication.” 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in sections 512 and 571 of the FD&C Act (21 U.S.C. 360b) have been approved under 0910–0032. The collections of information in 21 CFR 514.80 have been approved under 0910–0284.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification of the National Customs Automation Program Test Regarding Periodic Monthly Statements

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

ACTION: General notice.

SUMMARY: This document announces a change to the U.S. Customs and Border Protection’s (CBP) National Customs Automation Program (NCAP) test concerning Periodic Monthly Statements to reflect that test participants must transmit the payment of supplemental duty bills resulting from an underpayment of estimated duties, taxes, and fees electronically via Automated Clearinghouse (ACH). Except to the extent expressly announced or modified by this document, all aspects, rules, terms and

conditions announced in previous notices regarding the test remain in effect. For ease of reference, CBP is reproducing the entire test, with changes, in this document.

DATES: The modification announced in this test will become operational on December 15, 2025.

ADDRESSES: Comments concerning this test program may be submitted via email to Ryan Archer at ACECollections@cbp.dhs.gov with a subject line identifier reading, “Periodic Monthly Statements.”

FOR FURTHER INFORMATION CONTACT: For policy-related questions pertaining to ACH payment capabilities, contact Ryan Archer, Cargo Section Chief, Revenue Division at (317) 298–1200, ext. 1098 or at ACH-CUSTOMS@cbp.dhs.gov. For policy-related questions pertaining to billing, contact Jessica Vandemark, Financial Risk and Analysis Section Chief, Revenue Division at (317) 614–4811 or at billinginquiry@cbp.dhs.gov. For technical questions related to transmissions using the Automated Broker Interface (ABI), contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to the Client Services Division at gmb.clientreputreach@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION: On February 4, 2004, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** that announced a plan to conduct a test concerning Periodic Monthly Statements (hereinafter, referred to as the “PMS test”). The PMS test allows an importer or an importer’s designated broker to deposit estimated duties, taxes, and fees on a monthly basis via Automated Clearinghouse (ACH) payment processes. See 69 FR 5362 (February 4, 2004). CBP modified and clarified the PMS test in fourteen (14) subsequent **Federal Register** notices published on: September 8, 2004 (69 FR 54302); February 1, 2005 (70 FR 5199); August 8, 2005 (70 FR 45736); September 22, 2005 (70 FR 55623); January 20, 2006 (71 FR 3315); June 2, 2006 (71 FR 32114); October 17, 2008 (73 FR 61891); December 12, 2016 (81 FR 89482); January 9, 2017 (82 FR 2385); January 17, 2017 (82 FR 4901); June 8, 2017 (82 FR 26699); June 30, 2017 (82 FR 29910); November 1, 2017 (82 FR 50656); and September 5, 2019 (84 FR 46749).

In addition to payment of estimated duties, taxes, and fees on a monthly basis, PMS test participants may also owe supplemental duties resulting from an underpayment of estimated duties, taxes, and fees. Currently, such

¹ We note that this guidance document is relevant to new animal drugs with approved and conditionally approved claims. Emergency Use Authorizations under section 564 of the FD&C Act are outside the scope of this guidance.

supplemental duty bills can be paid by check. In order to promote operational efficiency of CBP's payment processes, this document modifies the PMS test to reflect that test participants must transmit electronic payment of supplemental duty bills resulting from an underpayment of estimated duties, taxes, and fees attributable to entries which were originally paid on a monthly basis through the PMS test. Accordingly, supplemental duty bills attributable to entries originally paid on a monthly basis through PMS may no longer be paid by check. Test participants must choose between ACH Debit and ACH Credit payment processes to pay supplemental duty bills. For payment of supplemental duty bills via ACH Debit, test participants must establish a *Pay.gov* account and submit the electronic payment using *Pay.gov*. In order to make payments via ACH Credit, test participants must contact CBP at *ACH-CUSTOMS@cbp.dhs.gov* to obtain specific instructions for the payment. For both payment processes, test participants must provide the supplemental duty bill number and the payment amount being remitted for each bill. For additional details to pay supplemental duty bills by ACH Debit or ACH Credit, see <https://www.cbp.gov/trade/priority-issues/revenue/bill-payments>.

For ease of reference, this document republishes the PMS test in its entirety, with updates in section IV to reflect the modification made by this document in a new paragraph i., and a redesignation of paragraphs i. and j. to paragraphs j. and k., respectively.

I. Background on National Customs Automation Program

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement (NAFTA) Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE) as the electronic data interchange (EDI) system authorized by CBP. ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for CBP and all of its communities of interest.

The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality, which update the system and add new functionality.

II. Authorization for the Test

The Customs Modernization Act authorizes the Commissioner of CBP to conduct limited test programs or procedures designed to evaluate planned components of the NCAP. Section 101.9(b) of title 19 of the Code of the Federal Regulations (19 CFR 101.9(b)) provides for the testing of NCAP components. See T.D. 95–21 (60 FR 14211) (March 16, 1995).

III. Eligibility Criteria

To be eligible for participation in this test, importers and their designated brokers must:

1. Have the ability to connect to the internet;
2. Have the ability to make periodic payment via Automated Clearinghouse (ACH) Debit or ACH Credit;
3. Have the ability to file entry/entry summary via Automated Broker Interface (ABI);
4. Provide a bond covering the periodic payment of estimated duties, taxes, and fees; and
5. Maintain a good standing account with CBP.

IV. Description of the Test

Participants in the PMS test are required to schedule entries for monthly payment. A Periodic Monthly Statement will list Periodic Daily Statements that have been designated for monthly payment. CBP issues a Preliminary Periodic Monthly Statement for entries to test participants on a monthly basis. Test participants must then electronically deposit payment of the estimated duties, taxes, and fees attributable to the entries, with CBP, via ACH. Subsequently, CBP generates the Final Periodic Monthly Statement which serves as evidence of the payment of the Preliminary Periodic Monthly Statement through an ACH transaction. CBP offers two ACH payment options, ACH Debit and ACH Credit. Persons wishing to participate in the PMS test must enroll in either the ACH Debit process or ACH Credit process by submitting the respective information to CBP.¹

¹ CBP Form 400 for the ACH Debit application and CBP Form 401 for the ACH Credit application may be found on *CBP.gov*. The forms may either be

CBP allows all entries currently eligible for placement on a Daily Statement to be placed on a Periodic Daily Statement, with the exception of reconciliation entries, United States-Mexico-Canada Agreement (USMCA) duty deferral entries, and entries requiring the payment of excise taxes. Entries scheduled for monthly payment will be processed as follows:

a. As entries are filed with CBP, the importer or the importer's designated broker schedules them for monthly payment.

b. CBP posts all entries that are scheduled for monthly payment on the Preliminary Periodic Daily Statement.

c. The importer or the importer's designated broker processes entry summary presentation transactions for each Preliminary Periodic Daily Statement within 10 working days of the date of entry.

d. After summary information has been filed, CBP posts the scheduled entries on the Final Periodic Daily Statement.

e. Entries appearing on the Final Periodic Daily Statement and scheduled for monthly payment appear on the Preliminary Periodic Monthly Statement. CBP will generate the Preliminary Periodic Monthly Statement by the 11th calendar day of the month following the month in which the merchandise is either entered or released, whichever comes first, unless the importer or the importer's designated broker selects an earlier date.

f. ACH Debit participants are required to submit one debit authorization for each Preliminary Periodic Daily Statement at any time from the creation of the Preliminary Periodic Daily Statement until the creation of the related Preliminary Periodic Monthly Statement. If an ACH Debit participant fails to submit an ACH Debit authorization for a Preliminary Periodic Daily Statement within 10 working days of the date of entry, payment for the Preliminary Periodic Daily Statement is considered late; however, the ACH Debit participant will still be permitted to submit the ACH Debit authorization. CBP will transmit the debit authorizations compiled in the Preliminary Periodic Monthly Statement to the financial institution on the 15th working day of the month following the month in which the merchandise is either entered or released, whichever comes first, unless the importer or the importer's designated broker selects an earlier date. ACH Debit participants must ensure that the money amount

emailed to CBP at *ACH-Customs@cbp.dhs.gov* or mailed to CBP at the address provided on *CBP.gov*.

identified on the Preliminary Periodic Monthly Statement is, in fact, available in their bank account by the 15th working day of that month.

g. For ACH Credit participants, CBP must receive the ACH Credit payment no later than the 15th day of the month following the month in which the merchandise scheduled for monthly processing is either entered or released, whichever comes first, or if that day falls on a weekend or holiday, the business day directly preceding such weekend or holiday, unless the importer or the importer's designated broker selects an earlier date.

h. For both ACH Debit and ACH Credit participants, once CBP receives confirmation from the Department of the Treasury that the funds are available and transferred to CBP (which marks the completion of the funds transfer), then CBP will: (1) issue the Final Periodic Monthly Statement and identify it as paid; (2) transmit the Final Periodic Monthly Statement to the importer or the importer's designated broker; and (3) treat the date of CBP's acceptance of the ACH Debit or ACH Credit payment as the effective payment date of the Periodic Monthly Statement for purposes of the calculation of interest and/or liquidated damages, if applicable. CBP will generate the Final Periodic Monthly Statement on the night that payment is processed.

i. CBP will issue a supplemental duty bill via a CBP Bill Form reflecting the difference between the duties, taxes, and fees assessed by CBP at liquidation of an entry and the total estimated duties, taxes, and fees deposited by the importer or the importer's designated broker. Test participants must transmit electronic payment of supplemental duty bills resulting from the underpayment of estimated duties, taxes, and fees via ACH Debit or ACH Credit. For payment of supplemental duty bills via ACH Debit, test participants must establish a *Pay.gov* account and submit the electronic payment using *Pay.gov*. For payment of supplemental duty bills via ACH Credit, test participants must contact CBP at *ACH-CUSTOMS@cbp.dhs.gov* to obtain specific instructions for payment. For both ACH payment processes, test participants must provide the supplemental duty bill number and the payment amount being remitted for each bill. Additional information related to these electronic bill payment options can be found at <https://www.cbp.gov/trade/priority-issues/revenue/bill-payments>.

j. An importer or an importer's designated broker choosing to file a single entry involving split shipments

consistent with the provisions of 19 CFR 141.57(d)(1) or unassembled or disassembled entities consistent with the provisions of 19 CFR 141.58(d)(1) may pay estimated duties, taxes, and fees attributable to those entries through the method set forth in the PMS test. The date of filing of that entry identifies the month in which entry is filed and establishes the obligation to pay estimated duties, taxes, and fees by the 15th working day of the month following the month in which entry is filed.

k. An importer or an importer's designated broker choosing to file incremental entries involving split shipments consistent with the provisions of 19 CFR 141.57(d)(2) or unassembled or disassembled entities consistent with the provisions 19 CFR 141.58(d)(2) as a special permit for immediate delivery after the arrival of the first portion (Incremental Release) also may pay estimated duties, taxes, and fees attributable to that entry through the method set forth in the PMS test. The date that the importer or the importer's designated broker obtains release of the first portion of the entry (as provided in 19 CFR 141.57(e) or 19 CFR 141.58(e)) will identify the month that the entry is filed and establishes the obligation to pay estimated duties, taxes, and fees by the 15th working day of the month following the month in which entry is filed.

Participants should note that if they voluntarily remove an entry from a Periodic Daily Statement before expiration of the 10-working-day period after release, that entry may be placed on another Periodic Daily Statement falling within the same 10-working-day period. If, however, participants remove an entry from a Periodic Daily Statement after expiration of the 10-working-day period after release, the entry may be the subject of a claim for liquidated damages for late payment.

V. Misconduct Under the Test

If a test participant fails to follow the terms and conditions of this test, fails to exercise reasonable care in the execution of participant obligations, fails to abide by applicable laws and regulations, fails to deposit duties, taxes, and fees in a timely manner, misuses the ACE Portal, engages in any unauthorized disclosure or access to the ACE Portal, or engages in any activity which interferes with the successful evaluation of the technology, the participant may be subject to civil and criminal penalties, administrative sanctions, liquidated damages, and/or suspension from this test.

Suspensions for misconduct will be administered by the Director, Revenue Division. A notice proposing suspension will be provided in writing to the participant. Such notice will apprise the participant of the facts or conduct warranting suspension and will inform the participant of the date that the suspension will begin. Any decision proposing suspension of a participant may be appealed to the Director, Revenue Division, within 15 calendar days of the notification date. Should the participant appeal the notice of proposed suspension, the participant must address the facts or conduct charges contained in the notice and state how compliance will be achieved. In cases of non-payment, late payment, willful misconduct or where public health interests or safety are concerned, the suspension may be effective immediately.

VI. Confidentiality

Data submitted and entered into ACE may include confidential commercial or financial information which may be protected under the Trade Secrets Act (18 U.S.C. 1905), the Freedom of Information Act (5 U.S.C. 552), and the Privacy Act (5 U.S.C. 552a). However, participation in this or any of the previous ACE tests is not confidential and, therefore, upon receipt of a written Freedom of Information Act request, the name(s) of an approved participant(s) will be disclosed by CBP in accordance with 5 U.S.C. 552.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB). In accordance with the requirements of the PRA, the ACH information collection, under OMB control number 1651-0078, will be updated to inform respondents how to voluntarily participate in the PMS test, and submitted to OMB for approval.

ACH Debit

Estimated Number of Respondents: 6,710.

Estimated Number of Total Annual Responses: 6,710.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 559.

ACH Credit

Estimated Number of Respondents: 144.

Estimated Number of Total Annual Responses: 144.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 12.

VIII. Suspension of Regulations

For purposes of this test, any provision in title 19 of the CFR including, but not limited to, the provisions found in parts 24, 141, 142, and 143 thereof relating to entry summary filing and processing that are inconsistent with the requirements set forth in this notice are waived for the duration of the test. See 19 CFR 101.9(b). This document does not waive any recordkeeping requirements found in 19 CFR part 163 and the Appendix to part 163 (commonly known as the “(a)(1)(A) list”).

Susan S. Thomas,

*Acting Executive Assistant Commissioner,
Office of Trade.*

[FR Doc. 2025–19572 Filed 10–15–25; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY**Immigration Parole Fee Required by HR–1 Reconciliation Bill**

AGENCY: U.S. Department of Homeland Security.

ACTION: Notice of immigration fee.

SUMMARY: The Department of Homeland Security (DHS) is announcing the implementation of the parole fee established in HR–1. Specifically, this notice announces the new immigration parole fee of \$1,000 for any alien who is paroled into the United States who does not meet an exception. Through this notice, DHS notifies the public that DHS will begin assessing and collecting this fee as required by HR–1.

DATES: This action is effective on October 16, 2025. The parole fee will apply for any alien that has a request for parole filed or pending prior to the effective date of this notice because the fee attaches when an alien is paroled into the United States.

FOR FURTHER INFORMATION CONTACT: Contacts for each component:

Office of Regulatory Affairs and Policy, U.S. Immigration and Customs Enforcement, Department of Homeland Security, 500 12th Street SW, Washington, DC 20536; telephone (202) 732–6960 (not a toll-free call).

Office of Chief Financial Officer, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746, telephone (240) 721–3000 (not a toll-free number).

Office of Field Operations, U.S. Customs and Border Protection, Department of Homeland Security, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, email address: parolenotification@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background and Authority**

On July 4, 2025, the President signed into law the One Big Beautiful Bill Act, Public Law 119–21, 139 Stat. 72 (HR–1). HR–1 was a comprehensive legislative package that changed many laws and added new laws that touch many areas of the United States Government. Among those changes, the law established several new fees related to immigration enforcement and lawful immigration programs.¹ The new immigration fees codified in HR–1 will be imposed on aliens in addition to any other fees authorized by law and by the Secretary of Homeland Security.² The fees are set for Fiscal Year (FY) 2025 and are, as established by statute, subject to annual increases based on the Consumer Price Index for All Urban Consumers.³

DHS has already issued three notices implementing the new fees.⁴ The U.S. Citizenship and Immigration Services (USCIS) notice issued on July 22, 2025, noted that DHS was not announcing the immigration parole fee at that time because the multiple exceptions needed additional consideration.⁵ DHS reviewed the exceptions and now believes that the fee can be implemented without further delay. This notice, therefore, implements the immigration parole fee. U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement (ICE), and USCIS will issue appropriate guidance and create or update forms, if necessary.

II. Parole

The Immigration and Nationality Act (“INA”) confers upon the Secretary of Homeland Security (“Secretary”) the

¹ See HR–1, Title X, Subtitle A, Part I, sections 100001 through 100018.

² See *id.*

³ See *id.*

⁴ USCIS Immigration Fees Required by HR–1 Reconciliation Bill, 90 FR 34511 (July 22, 2025) (USCIS Notice); CBP Immigration Fees Required by HR–1 for Fiscal Year 2025, 90 FR 42025 (Aug. 28, 2025); and Certain DHS Immigration Enforcement-Related Fees Required by HR–1 Reconciliation Bill, 90 FR 43223 (Sept. 8, 2025).

⁵ See 90 FR 34511 at 34516.

discretionary authority to parole an applicant for admission into the United States “temporarily under such conditions as [DHS] may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit.”⁶ Moreover, an applicant for admission in DHS custody may be released pursuant to a parole under INA sec. 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A), for urgent humanitarian reasons or significant public benefit as long as the alien presents “neither a security risk nor a risk of absconding.”⁷ When the purpose of the temporary, discretionary parole has been served, the alien is required to “return or be returned to the custody from which he was paroled and thereafter his case shall continue to be dealt with in the same manner as that of any other applicant for admission to the United States.”⁸

DHS may authorize parole for aliens outside the United States who must travel to a U.S. port of entry to seek parole.⁹ However, CBP has final discretionary authority to grant parole to aliens who appear for inspection at a U.S. port of entry.¹⁰ USCIS and ICE have final discretionary authority to grant parole to any alien applicant for admission within their responsibility who is physically present in the United States.¹¹

III. New Immigration Parole Fee

This notice announces the imposition and collection of the new immigration parole fee of \$1,000 for FY 2025 pursuant to HR–1. The fee must be paid by “any alien who is paroled into the United States.”¹² DHS interprets this to

⁶ See INA 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A); see also 8 CFR 212.5(a) and (c) through (e) (discretionary authority for establishing conditions of parole and for terminating parole).

⁷ 8 CFR 212.5(b).

⁸ INA 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A).

⁹ 8 CFR 212.5(f).

¹⁰ See *Memorandum of Agreement Between United States Citizenship and Immigration Services (USCIS), United States Immigration and Customs Enforcement (ICE), and United States Customs and Border Protection (CBP) for the Purpose of Coordinating the Concurrent Exercise by USCIS, ICE, and CBP, of the Secretary’s Parole Authority Under INA sec. 212(d)(5)(A) with Respect to Certain Aliens Located Outside of the United States*, dated Sept. 29, 2008 (relating to USCIS’s, ICE’s, and CBP’s concurrent exercise of parole authority and the framework governing which DHS component is to exercise jurisdiction over parole requests).

¹¹ See *id.*

¹² See Public Law 119–21 sec. 100004. See Markup of legislative proposals to comply with the reconciliation directive included in section 2001 of the Concurrent Resolution on the Budget for Fiscal Year 2025, H. Con. Res. 14, April 30, 2025, at <https://www.congress.gov/event/119th-congress/house-event/118180> (last visited Sept. 12, 2025) (noting that the legislation is “a mandate to restore immigration integrity, security, and enforcement”).