

### A. Covered Noncitizens

This Order applies to persons traveling from Canada or Mexico (regardless of their country of origin) who would otherwise be introduced into a congregate setting in a POE or U.S. Border Patrol station at or near the U.S. land and adjacent coastal borders subject to certain exceptions detailed below; this includes noncitizens who do not have proper travel documents, noncitizens whose entry is otherwise contrary to law, and noncitizens who are apprehended at or near the border seeking to unlawfully enter the United States between POE. For purposes of this Order, I refer to persons covered by the Order as “covered noncitizens.”

### B. Exceptions

This Order does *not* apply to the following:

- U.S. citizens, U.S. nationals, and lawful permanent residents;<sup>107</sup>
- Members of the armed forces of the United States and associated personnel, U.S. government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, subject to required assurances;<sup>108</sup>
- Noncitizens who hold valid travel documents and arrive at a POE;
- Noncitizens in the visa waiver program who are not otherwise subject to travel restrictions and arrive at a POE;
- Unaccompanied Noncitizen Children;<sup>109</sup>
- Noncitizens who would otherwise be subject to this Order, who are permitted to enter the U.S. as part of a DHS-approved process, where the process approved by DHS has been documented and shared with CDC, and includes appropriate COVID-19 mitigation protocols, per CDC guidance; and
- Persons whom customs officers determine, with approval from a supervisor, should be excepted from this Order based on the totality of the circumstances, including consideration of significant law enforcement, officer and public safety, humanitarian, and public health interests. DHS will consult with CDC regarding the standards for such exceptions to help ensure consistency with current CDC

guidance and public health recommendations.

### C. APA, Review, and Termination

This Order shall be immediately effective. I consulted with DHS and other federal departments as needed before I issued this Order and requested that DHS continue to aid in the enforcement of this Order because CDC does not have the capability, resources, or personnel needed to do so.<sup>110</sup> As part of the consultation, DHS developed operational plans for implementing this Order. CDC has reviewed these plans and finds them to be consistent with the language of this Order directing that covered noncitizens spend as little time in congregate settings as practicable under the circumstances. In my view, DHS’s assistance with implementing the Order is necessary, as CDC’s other public health tools are not viable mechanisms given CDC resource and personnel constraints, the large numbers of covered noncitizens involved, and the likelihood that covered noncitizens do not have homes in the United States.<sup>111</sup>

This Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA). Even if it were, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this Order and a delayed effective date. Given the public health emergency caused by COVID-19, it would be impracticable and contrary to public health practices and the public interest to delay the issuing and effective date of this Order with respect to all covered noncitizens. In addition, this Order concerns ongoing discussions with Canada and Mexico on how best to control COVID-19 transmission over our shared borders and therefore directly “involve[s] . . . a . . . foreign affairs function of the United States;”<sup>112</sup> thus, notice and comment and a delay in effective date are not required.

This Order shall remain effective until either the expiration of the Secretary of HHS’ declaration that COVID-19 constitutes a public health emergency, or I determine that the danger of further introduction, transmission, or spread of COVID-19 into the United States has ceased to be a serious danger to the

public health and continuation of this Order is no longer necessary to protect public health, whichever occurs first. At least every 60 days, the CDC shall review the latest information regarding the status of the COVID-19 public health emergency and associated public health risks, including migration patterns, sanitation concerns, and any improvement or deterioration of conditions at the U.S. border, to determine whether the Order remains necessary to protect public health. Upon determining that the further introduction of COVID-19 into the United States is no longer a serious danger to the public health necessitating the continuation of this Order, I will publish a notice in the **Federal Register** terminating this Order. I retain the authority to modify or terminate the Order, or its implementation, at any time as needed to protect public health.

### Authority

The authority for this Order is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and 42 CFR 71.40.

Dated: August 3, 2021.

**Sherri Berger,**

*Chief of Staff, Centers for Disease Control and Prevention.*

[FR Doc. 2021–16856 Filed 8–3–21; 4:15 pm]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10148 and CMS–10784]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our

<sup>107</sup> 42 CFR 71.40(f).

<sup>108</sup> 42 CFR 71.40(e)(1) and (3).

<sup>109</sup> As excepted pursuant to the Public Health Determination Regarding an Exception for Unaccompanied Noncitizen Children from Order Suspending the Right to Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease Exists. 86 FR 38717 (July 22, 2021).

<sup>110</sup> 42 U.S.C. 268; 42 CFR 71.40(d).

<sup>111</sup> CDC relies on the Department of Defense, other federal agencies, and state and local governments to provide both logistical support and facilities for federal quarantines. CDC lacks the resources, manpower, and facilities to quarantine covered noncitizens.

<sup>112</sup> 5 U.S.C. 553(a)(1).

burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by October 4, 2021.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: \_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10148 HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form

CMS-10784 The Home Health Care CAHPS® Survey (HHCAPHS) Mode Experiment

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection*

*Request:* Extension of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The Secretary of Health and Human Services (HHS), hereafter known as "The Secretary," codified 45 CFR parts 160 and 164 Administrative Simplification provisions that apply to the enforcement of the Health Insurance Portability and Accountability Act of 1996 Public Law 104-191 (HIPAA). The provisions address rules relating to the investigation of non-compliance of the HIPAA Administrative Simplification code sets, unique identifiers, operating rules, and transactions. 45 CFR 160.306, Complaints to the Secretary, provides for investigations of covered entities by the Secretary. Further, it outlines the procedures and requirements for filing a complaint against a covered entity.

Anyone can file a complaint if he or she suspects a potential violation. Persons believing that a covered entity is not utilizing the adopted Administrative Simplification provisions of HIPAA are voluntarily requested to file a complaint with CMS via the Administrative Simplification Enforcement and Testing Tool (ASETT) online system, by mail, or by sending an email to the HIPAA mailbox at [hipaacomplaint@cms.hhs.gov](mailto:hipaacomplaint@cms.hhs.gov). Information provided on the standard form will be used during the investigation process to validate non-compliance of HIPAA Administrative Simplification provisions.

This standard form collects identifying and contact information of the complainant, as well as the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to

the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings. *Form Number:* CMS-10148 (OMB control number: 0938-0948); *Frequency:* Occasionally; *Affected Public:* Private sector, Business or Not-for-profit institutions, State, Local, or Tribal Governments, Federal Government, Not-for-profits institutions; *Number of Respondents:* 21; *Total Annual Responses:* 21; *Total Annual Hours:* 12. (For policy questions regarding this collection contact Kevin Stewart at 410-786-6149).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control); *Title of Information Collection:* The Home Health Care CAHPS® Survey (HHCAPHS) Mode Experiment; *Use:* The reporting of quality data by HHAs is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act ("the Act"). This statute requires that "each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause." HHCAPHS data are mandated in the Medicare regulations at 42 CFR 484.250(a), which requires HHAs to submit HHCAPHS data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. This collection of information is necessary to be able to test updates to the HHCAPHS survey and administration protocols.

CMS proposes to conduct a mode experiment with the main goal of testing the effects of a web-based mode on response rates and scores as an addition to the three currently approved modes (OMB Control Number: 0938-1370). The addition of a web mode will give HHAs an alternative or an addition to the use of mail and telephone modes. CMS is also interested in testing a revised, shorter version of the HHCAPHS survey, based on feedback from patients and stakeholders.

The data collected from the HHCAPHS Survey mode experiment will be used for the following purposes:

- Test the shortened survey instrument, including several new items;
- Compare survey responses across the four proposed modes to determine if adjustments are needed to ensure that data collection mode does not influence results; and
- Determine if and by how much patient characteristics affect the patients' rating of the care they receive

and adjust results based on those factors.

The mode experiment is designed to examine the effects of the shortened survey on response rates and scores and to provide precise adjustment estimates for survey items and composites on the shortened survey instrument. Information from this mode experiment will help CMS determine whether an additional mode of administration (*i.e.*, Web data collection) should be included and a shortened survey instrument should be used in the current national implementation of the HHCAPHS Survey. *Form Number:* CMS-10784 (OMB control number: 0938-New); *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 6,280; *Total Annual Responses:* 6,280; *Total Annual Hours:* 1,049. (For policy questions regarding this collection contact Lori E. Teichman at 410-786-6684).

Dated: August 2, 2021.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-P-0271]

#### **Determination That VOTRIENT (Pazopanib Hydrochloride) Tablets, 400 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that VOTRIENT (pazopanib hydrochloride) tablets, 400 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for pazopanib hydrochloride tablets, 400 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6212, Silver Spring, MD 20993-0002, 240-402-9674, [Sungjoon.Chi@fda.hhs.gov](mailto:Sungjoon.Chi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, are the subject of NDA 022465, held by Novartis Pharmaceuticals Corp., and initially approved on October 19, 2009. VOTRIENT is a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma. VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated March 5, 2021 (Docket No. FDA-2021-P-0271), under 21 CFR 10.30, requesting that the Agency determine whether VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to VOTRIENT (pazopanib hydrochloride) tablets, 400 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 29, 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-2018-N-3741]

#### **Remanufacturing of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period**

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

**ACTION:** Notice of availability; extension of comment period.