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**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-P-3849]

#### Determination That OZEMPIC (Semaglutide) Solution, 2 Milligrams Per 1.5 Milliliters Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA or Agency) has determined that OZEMPIC (semaglutide) solution, 2 milligrams (mg)/1.5 milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Neerja Razdan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, (240) 402-1556, [Neerja.Razdan@fda.hhs.gov](mailto:Neerja.Razdan@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, is the subject of NDA 209637, held by Novo Nordisk Inc., and initially approved on December 5, 2017. OZEMPIC is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease; to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book. Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated September 15, 2025 (Docket No. FDA-2025-P-3849), under 21 CFR 10.30, requesting that the Agency determine whether OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, was 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 OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of

OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, 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 OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, 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 OZEMPIC (semaglutide) solution, 2 mg/1.5 mL, 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.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2026-N-0499]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

**AGENCY:** Food and Drug Administration, 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 June 1, 2026.

**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 0910–0466. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8758, [PRStaff@fda.hhs.gov](mailto:PRStaff@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.

**Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice—21 CFR Part 120**

OMB Control Number 0910–0466—*Extension*

This information collection supports FDA’s regulations in part 120 (21 CFR part 120), which govern the application of HACCP principles to the processing of fruit and vegetable juices. HACCP is

a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA’s statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Specifically, regulations in 21 CFR 120.12 provide for records documenting the establishment, implementation, and continued application of a HACCP system. The rationale in establishing a HACCP system of preventive controls is to design and check the process so that the final product is not contaminated. Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

HACCP records are retained by respondents and presented to FDA upon inspection. We use the information to

determine compliance with applicable requirements. Products not in compliance with applicable statutory and regulatory requirements may be adulterated under the FD&C Act and subject to enforcement action.

In an effort to reduce burden and assist respondents, our website (<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp>) offers guidance for industry, training and education, and background information to assist the food industry in developing and implementing a Juice HACCP. All agency guidance documents are issued in accordance with our good guidance practice regulation in 21 CFR 10.115, which provides for public comment at any time.

*Description of Respondents:* Respondents to this information collection are processors of fruit and vegetable juices (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers).

In the **Federal Register** of February 20, 2026 (91 FR 8251), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.6(c) and 120.12(a)(1) and (b); written monitoring and correction records for Sanitation Standard Operating Procedures.	1,875	365	684,375	0.1(6 minutes) .....	68,438
120.7; 120.10(a); and 120.12(a)(2), (b) and (c); require written hazard analysis of food hazards.	2,300	1.1	2,530	20 .....	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); record-keeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01 (1 minute) .....	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); document all corrective actions taken in response to a deviation from a critical limit.	1,840	12	22,080	0.1 (6 minutes) .....	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12(a)(5) and (b); records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1 (6 minutes) .....	9,568
120.11(b) and (c); and 120.12(a)(5) and (b); record validation that the HACCP plan is adequate to control food hazards that are likely to occur.	1,840	1	1,840	4 .....	7,360
120.11(c) and 120.12(a)(5) and (b); document revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur).	1,840	1	1,840	4 .....	7,360

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.14(a)(2), (c), and (d) and 120.12(b); importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120.	308	1	308	4 .....	1,232
120.8(a), 120.8(b), and 120.12(a)(3), (b), and (c); written HACCP plan.	1,560	1.1	1,716	60 .....	102,960
Total .....	.....	.....	21,980,369	.....	461,426

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

Based on a review of the information collection since its last OMB approval, we have made no adjustments to our burden estimate.

**Grace R. Graham,**  
Deputy Commissioner for Policy, Legislation,  
and International Affairs.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2026–N–1321]

**ChemoCentryx, Inc.; Proposal To Withdraw Approval of New Drug Application for TAVNEOS (Avacopan) Capsule, 10 Milligrams; Opportunity for a Hearing**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration’s (FDA, Agency, or we) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of the new drug application (NDA) for TAVNEOS (avacopan) capsule, 10 milligrams (mg), held by ChemoCentryx, Inc., One Amgen Center Dr., Thousand Oaks, CA 91320 (ChemoCentryx or applicant), and is announcing an opportunity for the applicant to request a hearing on this proposal. The grounds for the proposal are twofold: (i) on the basis of new information before FDA, evaluated together with the evidence available to FDA when the application was approved, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; and (ii) the application

contains untrue statements of material fact.

**DATES:** The applicant may submit a written request for a hearing by June 1, 2026 and submit all data, information, and analyses in support of the hearing request by June 29, 2026. Others may submit electronic or written comments by June 29, 2026.

**ADDRESSES:** The request for a hearing may be submitted by the applicant by either of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to <https://www.regulations.gov>, including any attachments to the request for a hearing, will be posted to the docket unchanged.

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. The request for a hearing must include the Docket No. FDA–2026–N–1321 for “ChemoCentryx, Inc.; Proposal to Withdraw Approval of New Drug Application for TAVNEOS (Avacopan) Capsule, 10 Milligrams; Opportunity for a Hearing.” The request for a hearing

will be placed in the docket and publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. The applicant may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- **Confidential Submissions—**To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov> or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

*Comments Submitted by Other Interested Parties:* For all comments submitted by other interested parties, submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to