

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket Nos. FDA–2024–N–2381, FDA–2024–N–2019, FDA–2014–N–0987, FDA–2024–N–1382, and FDA–2022–N–1894]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information

collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Medical Device Recall Authority .....	0910–0432	3/31/2028
Guidance for Industry and FDA Staff; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle .....	0910–0594	3/31/2028
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications .....	0910–0796	3/31/2028
Electronic User Fee Payment Form Requests .....	0910–0805	3/31/2028
Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey .....	0910–0912	3/31/2028

Dated: June 26, 2025.

**Grace R. Graham,**

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

[FR Doc. 2025–12414 Filed 7–2–25; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA–2025–P–0333]

**Determination That SYNDROS (Dronabinol) Solution, 5 Milligrams/ Milliliter, 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, Agency, or we) has determined that SYNDROS (dronabinol) solution, 5 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for SYNDROS (dronabinol) solution, 5 mg/mL, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, [Awo.Archampong-Gray@fda.hhs.gov](mailto:Awo.Archampong-Gray@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.

SYNDROS (dronabinol) solution, 5 mg/mL, is the subject of NDA 205525, held by Chartwell Scheduled, LLC, and initially approved on July 1, 2016. SYNDROS is indicated in adults for the treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome; and of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

SYNDROS (dronabinol) solution, 5 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 20, 2025 (Docket No. FDA–2025–P–0333), under 21 CFR 10.30, requesting that the Agency determine whether SYNDROS (dronabinol) solution, 5 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.