- MR0000268.PD14: ZYN Cinnamon 6 mg
- MR0000268.PD15: ZYN Smooth 3 mg [2]
- MR0000268.PD16: ZYN Smooth 6 mg [3]
- MR0000268.PD17: ZYN Chill 3 mg [4]
- MR0000268.PD18: ZYN Chill 6 mg [5]
- MR0000268.PD19: ZYN Menthol 3 mg [6]
- MR0000268.PD20: ZYN Menthol 6 mg [7]

Discussion generally will focus on evidence related to the relative health risks of the products, consumer understanding and perceptions of the applicant's proposed modified risk claim, and the potential public health impact of a modified risk marketing order.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the time of the advisory committee meeting and be posted on FDA's website after the meeting. Background material and the link to the online video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. ET on January 22, 2026. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, phone numbers, and email addresses of proposed participants, on or before 12 p.m. ET on December 31, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 5, 2026.

For press inquiries, please contact the FDA Newsroom at *www.fda.gov/news-events/fda-newsroom.*

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rachel Jang, PharmD, DFO (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Lowell M. Zeta,

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

[FR Doc. 2025–20768 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

[2] Swedish Match might also market this product as ZYN Original 3 mg.

[3] Swedish Match might also market this product as ZYN Original 6 mg.

[4] Swedish Match might also market this product as ZYN Classic 3 mg.

[5] Swedish Match might also market this product as ZYN Classic 6 mg.

[6] Swedish Match might also market this product as ZYN Fresh 3 mg.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1108]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program

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 December 24, 2025.

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 0910–0375. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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.*

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.

Third-Party Review Program

OMB Control Number 0910–0375—Extension

Section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directs FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 510(k) third party (3P510k) review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a

request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

Respondents to this information collection are businesses or government and can be for-profit or not-for-profit organizations, such as third party review organizations.

The guidance ''510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations'' (March 2020) was intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k program and third party review of Emergency Use Authorization (EUA) requests by describing FDA's expectations for the review of 510(k) submissions and EUA requests by third party review organizations. This guidance document also reflects section 523 of the FD&C Act, which directs FDA to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. This guidance was superseded on November 21, 2024, when FDA issued the final guidance ''510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations'' (November 2024) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review*). The guidance also includes new content that outlines how FDA may contract with third party review organizations to perform reviews of EUA requests (3PEUA review) when appropriate emergency declaration authorities are active under section 564 of the FD&C Act. (See OMB Control Number 0910–0595.)

In the **Federal Register** of July 3, 2025 (90 FR 29552), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; guidance document section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation (initial); Section V.D	1	1	1	40	40
Requests for accreditation (re-recognition); Section V. D	3	1	3	24	72
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	40	5,040
Complaints; Section V.C	1	1	1	0.25 (15 minutes)	0.25
Total					5,152.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews conducted by 3PROs; Section V. B	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section V. C	9	1	9	1	9
Recordkeeping system regarding complaints; Section V. C	9	1	9	2	18
Total					1,287

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Upon review of this information collection, we have adjusted our burden estimate for the average burden hours required per response for initial requests for accreditation from 24 to 40 hours to more accurately reflect the time required based on recent experience of FDA program staff. This adjustment has resulted in an increase of 15 hours to the currently approved burden.

Lowell M. Zeta,

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

[FR Doc. 2025–20772 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–5139; FDA–2024–E–5140; FDA–2024–E–5141]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENVISION MAMMOGRAPHY PLATFORM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ENVISION MAMMOGRAPHY PLATFORM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 23, 2026. Furthermore, any interested person may