U.S. FOOD & DRUG ADMINISTRATION

March 2, 2026

Tammy Dean
Senior Regulatory Affairs Manager
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Re: Revocation of EUA200514

Dear Tammy Dean:
This letter is in response to the request from Roche Diagnostics, in an email dated February 6, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Elecsys Anti-SARS-CoV-2 issued on May 2, 2020, revised and reissued on May 19, 2021, and amended on June 4, 2020, July 21, 2020, October 23, 2020, July 13, 2021, September 23, 2021, and December 17, 2021. FDA understands that as of the date of this letter there are no viable EUA Elecsys Anti-SARS-CoV-2 reagents remaining in distribution in the United States. As of the date of this letter, Roche Diagnostics has fully transitioned to the Elecsys Anti-SARS-CoV-2 product that was cleared under K250768.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Roche Diagnostics has requested that FDA revoke the EUA for the Elecsys Anti-SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200514 for the Elecsys Anti-SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Elecsys Anti-SARS-CoV-2 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–12906 Filed 6–25–26; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5827]

Agency Information Collection Activities; Proposed Collection; Comment Request; Time and Extent Applications for Nonprescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on time and extent

applications for nonprescription drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by August 25, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 25, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

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.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–5827 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Time and Extent Applications for Nonprescription Drug Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. 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 comments. 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.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Time and Extent Applications for Nonprescription Drug Products

OMB Control Number 0910–0688—Extension

I. Background

This information collection supports certain Agency regulations in part 330 (21 CFR part 330) regarding over-the-counter (OTC) human drugs and associated guidance. Specifically, FDA regulations in §§ 330.14 and 330.15 (21 CFR 330.14 and 330.15) establish additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded. These regulations provide that OTC drug products introduced into the U.S. market after the OTC drug review began in 1972 and OTC drug products without any marketing experience in the United States can be evaluated under the OTC monograph system if the conditions (*e.g.,* active

ingredients) meet certain ''time and extent'' criteria outlined in the regulations. The regulations in § 330.14 allow a sponsor to submit certain information to the Agency in a time and extent application (TEA) for use to determine eligibility of a condition for consideration in the OTC monograph system.

We developed the final guidance document entitled ''Time and Extent Applications for Nonprescription Drug Products'' (September 2011) (available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products*) to assist respondents with the information collection provisions found in the regulations. The guidance was issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to the Agency to request that a drug product be included in the OTC drug monograph system. The guidance also discusses format and content elements, and the process for submitting information, consistent with the applicable regulations.

II. OTC Monograph Reform in the Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act (Pub. L. 116–136, Stat. 281)) signed March 27, 2020, included provisions that govern the way certain OTC drugs are regulated in the United States. The CARES Act added section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which reforms and modernizes the OTC drug review process, including establishing new procedures for consideration of additions or changes to conditions covered in OTC monographs. As a result of these revised statutory provisions, we anticipate no submissions under § 330.14. Our OTC Monographs@FDA portal (*https://dps.fda.gov/omuf*) provides additional information about OTC monograph drugs and the OTC drug review process.

Consistent with section 505G(k)(3) of the FD&C Act, we plan to withdraw the regulations supporting the TEA provisions in part 330 and discontinue the related guidance document. When these actions occur, we will also request discontinuation of the information collection approved under OMB control number 0910–0688.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 330.14(c) and (d); Time and extent application and submission of information.	1	~1.29	1.29	861.78 hours (861 hours and 47 minutes).	1,112
§ 330.14(f) and (i); Submission of safety and effectiveness data, including data and information listed in § 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)), and an official or proposed compendial monograph (§ 330.14(i)).					
§ 330.14(j) and (k); Submitter correspondence with FDA.					

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

As previously stated, as a result of the CARES Act statutory provisions described above, we anticipate no TEA submissions. For purposes of burden calculation, we assume one respondent as a placeholder. The burden we attribute to reporting activities is assumed to be distributed among the individual elements.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12884 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Population based Research in Infectious Disease Study Section.

Date: July 21, 2026.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–443–7414, *snyderji@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; HIV/AIDS Intra- and Interpersonal Determinants and Behavioral Interventions Study Section.

Date: July 21–22, 2026.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, M.D. 20892.