Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2220, Silver Spring, MD 20993, 301–796–6636; Hilary Hoffman, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rm. 389, Rockville, MD 20855, 240–402–8406; Yuguang Wang, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A012, College Park, MD 20740, 240–402–1757; Hans Rosenfeldt, Office of Science, Center for Tobacco Products, Food and Drug Administration, 11785 Beltsville Dr., Calverton Tower, Rm. 5322, Beltsville, MD 20705, 301–796–2202; Eric S. Myskowski, Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, District Office—Minneapolis, 250 Marquette Ave., Minneapolis, MN 55401, 612–758–7187.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.'' The histopathological assessment of tissue samples is one of the key activities conducted during GLP-compliant nonclinical laboratory studies. Commonly, the histopathological assessment includes an initial evaluation of glass histology slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist, group of pathologists, or Pathology Working Group. The current regulations include general requirements for histopathology evaluation (*e.g.,* standard operating procedures), but the use of whole slide images in lieu of glass slides is not specifically addressed. This guidance provides information to sponsors and nonclinical laboratories regarding the management, documentation, and use of whole slide images during histopathology assessment and/or pathology peer review performed for GLP-compliant nonclinical toxicology studies using non-human specimens.

When whole slide images are used in lieu of glass slides as part of a nonclinical study conducted in compliance with the GLP regulations adequate documentation is critical. Documentation practices during whole slide imaging generation and use have not been clearly defined and vary among nonclinical testing facilities. This question-and-answer document is intended to clarify FDA's recommendations concerning the management, documentation, and use of whole slide imaging in histopathology assessment and/or pathology peer review for nonclinical studies conducted in compliance with the GLP regulations. Use of whole slide images in casual consultations, opinion exchanges, and mentoring among pathologists are not covered by this guidance document.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 regarding the good laboratory practice requirements for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: April 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07511 Filed 4–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1158]

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' As more medical devices are becoming interconnected, cybersecurity threats have become more numerous, more frequent, more severe, and more clinically impactful. As a result, ensuring medical device safety and effective includes adequate medical device cybersecurity, as well as its security as part of the larger system. In 2018, FDA proposed updates to the final guidance, ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,'' and issued a draft guidance of the same name. This draft guidance replaces the 2018 draft guidance. This draft guidance is intended to further emphasize the importance of ensuring that devices are designed securely, are designed to be capable of mitigating emerging cybersecurity risks throughout the Total Product Life Cycle, and to clearly outline FDA's recommendations for premarket submission content to address cybersecurity concerns. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 7, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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

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–2021–D–1158 for ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5410, Silver Spring, MD 20993–0002, 301–796–6937; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The need for effective cybersecurity to reasonably ensure medical device safety and effectiveness has become more important with the increasing use of wireless, internet- and network-connected devices, portable media (*e.g.,* USB or CD), and the frequent electronic exchange of medical device-related health information. In addition, cybersecurity threats to the healthcare sector have become more frequent, more severe, and carry increased potential for clinical impact. Cybersecurity incidents have rendered medical devices and hospital networks inoperable, disrupting the delivery of patient care across healthcare facilities in the United States and globally. Such cyber attacks and exploits can delay diagnoses and/or treatment and may lead to patient harm.

Although FDA issued guidance providing recommendations for device cybersecurity information in premarket submissions in 2014,[1] the rapidly evolving landscape, and the increased understanding of the threats and their potential mitigations, necessitate an updated approach. As such, FDA issued a draft guidance in 2018 entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.''

Given the rapidly evolving device cybersecurity landscape, FDA is issuing this draft guidance, which replaces the 2018 draft guidance, to further emphasize the importance of ensuring that devices are designed securely, are designed to be capable of mitigating emerging cybersecurity risks throughout the Total Product Life Cycle, and to clearly outline FDA's recommendations for premarket submission content to address cybersecurity concerns, including device labeling. These recommendations can facilitate an efficient premarket review process and help ensure that marketed medical devices are sufficiently resilient to cybersecurity threats.

This draft guidance supplants the draft guidance entitled, ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'' issued October 18, 2018, and takes into consideration comments received on the 2018 draft guidance (83 FR 52835;

[1] Content of Premarket Submissions for Management of Cybersecurity in Medical Devices—Guidance for Industry and Food and Drug Administration Staff at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.*

https://www.govinfo.gov/content/pkg/FR-2018-10-18/pdf/2018-22697.pdf) and input gained from the public workshop entitled, ''Content of Premarket Submissions for Management of Cybersecurity in Medical devices'' held on January 29–30, 2019.[2] Several changes were made in this draft guidance, including a change in title to better capture the scope of the current draft guidance, document structure change to align with use of a Secure Product Framework, removal of risk tiers, replacement of the Cybersecurity Bill of Materials with Software Bill of Materials, additional clarification regarding premarket submission document requests throughout the draft guidance, and addition of Investigational Device Exemptions to the scope.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This draft guidance is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1825–R1 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07614 Filed 4–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0077]

Determination That NASONEX (Mometasone Furoate) Nasal Spray, 0.05 Milligram/Spray (50 Microgram), 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 NASONEX (mometasone furoate) nasal spray, 0.05 milligram (mg)/spray (50 microgram (mcg)), 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: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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).

[2] *https://wayback.archive-it.org/7993/20201222110245/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-content-premarket-submissions-management-cybersecurity-medical-devices-january-29-30.*