

comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before September 3, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Proposed Consent Orders To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, two agreements containing consent orders from Aleksandr Kogan and Alexander Nix, individuals.

The proposed consent orders have been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreements and the comments received, and will decide whether it should withdraw from the agreements and take appropriate action or make final the agreements' proposed orders.

Aleksandr Kogan, until September 2018, was a Senior Research Associate and Lecturer at the Department of Psychology at the University of Cambridge in the United Kingdom. Kogan was also the developer of a Facebook application called the GSRApp, sometimes publicly referred to as the "thisisyourdigitallife" app.

Alexander Nix, until April 2018, was the Chief Executive Officer of Cambridge Analytica LLC and the head of SCL Elections Ltd.

The Commission's proposed complaint alleges that Kogan, together with the data analytics company, Cambridge Analytica, LLC, and its Chief

Executive Officer, Alexander Nix, used the GSRApp to harvest certain Facebook user profile data from approximately 250,000–270,000 Facebook users who directly interacted with the app ("App Users"), as well as 50–65 million of the "friends" in those users' Facebook social network. The proposed complaint alleges that Respondents obtained the App Users' consent to collect their Facebook profile data through false and deceptive means.

The Commission's proposed complaint alleges a violation of Section 5(a) of the Federal Trade Commission Act, specifically that Respondents' representation to App Users that it would not "download [their] name or any other identifiable information" was deceptive because the GSRApp, in fact, collected identifiable information from these users, including their Facebook User ID.¹

The proposed consent orders contain injunctive provisions addressing Kogan's and Nix's alleged unlawful conduct. Part I of the proposed consent orders prohibits Kogan and Nix from making false or deceptive statements regarding the extent to which they protect the privacy and confidentiality of Covered Information as defined in the proposed consent orders, including:

A. The extent to which they collect, use, share, or sell any Covered Information; and

B. The purposes for which they collect, use, share, or sell any Covered Information.

Part II of the proposed consent orders relates to the deletion and destruction of Covered Information collected through the GSRApp, and any information or work product, including any algorithms, derived from such Covered Information, and requires Kogan and Nix to:

A. Provide a written statement, sworn under penalty of perjury, with the name, address, and phone number for each person with whom they shared any

¹ The Commission also issued an administrative complaint against Cambridge Analytica alleging a similar deception count as well as two additional counts related to its participation in Privacy Shield, a framework that allows companies to transfer personal data lawfully from the European Union to the United States. The complaint alleges that representations on Cambridge Analytica's website that Cambridge Analytica participated in Privacy Shield after May 2018 were deceptive because the company did not take the steps necessary to renew Cambridge Analytica's certification when it expired in May 2018. The complaint also alleges that representations on Cambridge Analytica's website that Cambridge Analytica adheres to Privacy Shield's principles were deceptive because Cambridge Analytica failed to comply with Privacy Shield's requirement to affirm to the Commerce Department that the company would continue to apply the principles to personal information that it received during the time it participated in the program.

Covered Information collected from consumers through GSRApp, and any information or work product that originated, in whole or in part, from this Covered Information; and

B. Delete or destroy all Covered Information collected from consumers through the GSRApp, and any information or work product, including any algorithms or equations, that originated, in whole or in part, from this Covered Information, which destruction must generally occur within ten (10) days from the effective date of the proposed orders. Kogan and Nix must then provide a statement, sworn under penalty of perjury, confirming that the data has been destroyed or deleted.

Parts III through VII of the proposed consent orders are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Respondents to provide information or documents necessary for the Commission to monitor compliance. The proposed consent orders will be in effect for twenty (20) years.

The purpose of this analysis is to aid public comment on the proposed orders. It is not intended to constitute an official interpretation of the proposed complaint or proposed orders, or to modify in any way the proposed orders' terms.

By direction of the Commission.

April J. Tabor,
Acting Secretary.

[FR Doc. 2019–16372 Filed 7–31–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2330]

Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers; Draft Guidance for Industry; 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 a draft guidance for industry entitled "Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers." This draft guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during good laboratory practice (GLP)-

compliant toxicology studies. When pathology peer review occurs as part of a nonclinical laboratory study conducted in compliance with GLP regulations, it should be well-documented. However, documentation practices during pathology peer review have not been clearly defined and vary among nonclinical testing facilities. This question-and-answer (Q&A) draft guidance is intended to clarify FDA's recommendations concerning the management, conduct, and documentation of pathology peer review.

DATES: Submit either electronic or written comments on the draft guidance by September 30, 2019 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-2019-D-2330 for "Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers." 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.

- **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.gpo.gov/fdsys/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.

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for

Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Tahseen Mirza, Center for Drug Evaluation and Research, Office of Study Integrity and Surveillance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5330, Silver Spring, MD 20993, 301-796-7645; or Stephen Ripley, Office of the Center Director, 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; or Judy Davis, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993, 301-796-6636; or Hilary Hoffman, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Food and Drug Administration, 7500 Standish Place, Rm. 389, Rockville, MD, 20855, 240-402-8406; or Yuquang Wang, Center for Food Safety and Nutrition, Office of the Center Director, Food and Drug Administration, 5001 Campus Drive, Rm. 4A035, College Park, MD, 20740, 240-402-1757; or Kimberly Benson, Center for Tobacco Products, Office of Science, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 301-796-1327.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers." This draft guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during GLP-compliant toxicology studies.

The histopathological assessment of tissue samples is one of the key activities performed during GLP-compliant toxicology studies. Commonly, histopathological assessment includes an initial read of

tissue slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist. Pathology peer review may be particularly useful in situations where unique or unexpected findings are noted or when the reviewing pathologist has a particular expertise with a class of compounds. When pathology peer review occurs as part of a nonclinical laboratory study conducted in compliance with 21 CFR part 58 (GLP regulations), it should be well-documented in the study records. However, documentation practices during pathology peer review have not been clearly defined and vary among nonclinical testing facilities.

The GLP regulations include general requirements for histopathology evaluation (for example, it requires that standard operating procedures be established to cover histopathology), and pathology peer review can be valuable to the histopathology evaluation during a GLP study even though it is not specifically addressed in the GLP regulations. This Q&A draft guidance is intended to clarify FDA's recommendations concerning the management and conduct of pathology peer review when performed during GLP-compliant toxicology studies.

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 "Pathology Peer Review 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The following collections of information regarding GLP-compliant toxicology studies have been approved under OMB control number 0910–0119:

- § 58.29 related to personnel who conduct nonclinical laboratory studies;
- § 58.35 for preparing quality control units;
- § 58.81 for preparing and maintaining standard operating procedures for testing facilities;

pathology peer review should be planned, conducted, documented, and reported in accordance with established procedure;

- §§ 58.120, 58.185, and 58.190 for preparing a final report for each study, including a protocol and any changes to the protocol and for maintaining documentation, protocols, and final reports generated from nonclinical laboratory studies.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: July 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16361 Filed 7–31–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1662]

Vulvovaginal Candidiasis: Developing Drugs for Treatment; Guidance for Industry; 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 a final guidance for industry entitled "Vulvovaginal Candidiasis: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the overall clinical development program and clinical trial designs to support drugs for treating vulvovaginal candidiasis (VVC). This guidance incorporates the comments received for and finalizes the draft guidance for industry of the same name issued July 1, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on August 1, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2016–D–1662 for "Vulvovaginal Candidiasis: Developing Drugs for Treatment." 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.

- **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