practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on elemental impurities in animal drug products. 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

This guidance contains no collection 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.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: November 17, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25726 Filed 11–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1848]

Clinical Drug Interaction Studies With Combined Oral Contraceptives; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' This guidance assists sponsors of investigational new drug applications and new drug applications in evaluating the need for and design drug-drug interaction (DDI) studies involving combined oral contraceptives (COCs) during drug development as well as determining how to communicate the results and recommendations from the DDI studies. Specifically, this guidance focuses on the conduct of clinical studies to evaluate the DDI potential of an investigational drug on a COC, including the need for and design of the clinical studies and the interpretation of the study results.

DATES: Submit either electronic or written comments on the draft guidance by February 22, 2021 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–2020–D–1848 for ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' 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)).

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. 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: Lauren Milligan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3159, Silver Spring, MD 20903–0002, 301–796–5008, or *OCP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' COCs can effectively prevent pregnancy; however, the use of concomitant medications could result in DDIs that affect the safety and/or efficacy of COCs. For example, the induction of drug metabolizing enzymes could cause lower levels of progestin and/or estrogen and compromise the efficacy of COCs, while inhibition of metabolizing enzymes could cause higher levels of these hormones and increase the risk of safety events such as venous thromboembolism.

This draft guidance discusses when DDI studies with COCs should be conducted. It also provides recommendations on the design and conduct of such studies, including but not limited to the study population, the choice of COC, study design, pharmacokinetic sampling schedule, and pharmacodynamic assessments. This guidance discusses the interpretation of results from clinical DDI studies with COCs and whether it is possible to extrapolate the results of such studies to other COCs. Based on the study results, specific recommendations for labeling are provided. Decision trees regarding whether a DDI study with a COC is recommended based on the metabolizing enzyme inhibition or induction potential of the investigational drug are also included.

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 ''Clinical Drug Interaction Studies With Combined Oral Contraceptives.'' 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 for submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014; 0910–0001; and 0910–0338, respectively. In addition, the submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572.

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* or *https://www.regulations.gov.*

Dated: November 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25744 Filed 11–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Vaccines National Strategic Plan Available for Public Comment

AGENCY: Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft Vaccines National Strategic Plan 2021–2025 (Vaccine Plan) available for public comment. The draft Vaccine Plan may be reviewed at *www.hhs.gov/oidp.*

DATES: All comments must be received by 5:00 p.m. ET on December 3, 2020 to be considered.

ADDRESSES: All comments must be submitted electronically to *NVP.RFI@hhs.gov* to be considered.

FOR FURTHER INFORMATION CONTACT: David Kim, OIDP, *David.Kim@hhs.gov,* 202–795–7636.

SUPPLEMENTARY INFORMATION: The development of a National Vaccine Plan was mandated by Congress as a mechanism for the Director of the National Vaccine Program (as delegated by the Assistant Secretary for Health) to communicate priorities for achieving the Program's responsibilities of ensuring adequate supply of and access to vaccines and ensuring the effective and optimal use of vaccines. The most recent Plan, released in 2010, provided a comprehensive 10-year national strategy for enhancing all aspects of the plan, including vaccine research and development, supply, financing, distribution, and safety; informed decision-making by consumers and health care providers; vaccine-preventable disease surveillance; vaccine effectiveness and use monitoring; and global cooperation (*http://www.hhs.gov/nvpo/vacc_plan/index.html*). The 2010 Plan and the associated implementation plan (*https://www.hhs.gov/sites/default/files/nvpo/vacc_plan/2010-2015-Plan/implementationplan.pdf*) have played an important role in guiding strategies and allocations of resources with respect to vaccines and vaccination. However, since the publication of the 2010 Plan, there have been many changes in the vaccine landscape.

With U.S. vaccination rates above 90% for many childhood vaccines, most individuals have not witnessed firsthand the devastating illnesses against which vaccines offer protection, such as polio or diphtheria. According to a recent study, routine childhood immunizations among U.S. children born in 2009 will prevent 20 million cases of disease and 42,000 premature deaths, with a net savings of $13.5 billion in direct costs and $68.8 billion in total societal costs.[1] In contrast, adult vaccination coverage rates have remained persistently low, with only modest gains for certain populations in the past few years.[2] As a result, the standards for adult immunization practice were updated in 2014 to promote integration of vaccines into routine clinical care for adults.[3]

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[1] Zhou F. *et al.* Economic evaluation of the routine childhood immunization program in the United States, 2009. Pediatrics. 2014; 133: 1–9.

[2] *https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html.*

[3] National Vaccine Advisory Committee. Recommendations from the National Vaccine