TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Dexamethasone; Neomycin sulfate; Polymyxin b sulfate.
Enfuvirtide.
Eplontersen sodium.
Estrogens, conjugated.
Icatibant acetate.
Macitentan; Tadalafil.
Magnesium sulfate; Polyethylene glycol 3350; Potassium chloride; Sodium chloride; Sodium sulfate.
Memantine hydrochloride.
Mitomycin.
Paclitaxel.
Palovarotene.
Pemetrexed disodium.
Phentolamine mesylate.
Phytonadione (multiple reference listed drugs).
Quizartinib dihydrochloride.
Risperidone.
Ritlecitinib tosylate.
Treprostinil.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2.—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s).
Allopurinol.
Azelaic acid.
Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate.
Budesonide; Formoterol fumarate dihydrate.
Enzalutamide.
Ferric carboxymaltose.
Ferumoxytol.
Fluticasone propionate.
Fluticasone propionate; Salmeterol xinafoate.
Formoterol fumarate.
Formoterol fumarate; Mometasone furoate.
Labetalol hydrochloride.
Lenvatinib mesylate.
Levonorgestrel.
Liraglutide.
Losartan potassium.
Mometasone furoate.
Nepafenac (multiple reference listed drugs).
Nitroglycerin.
Olaparib.
Phytonadione (multiple reference listed drugs).
Primidone.
Rasagiline mesylate.
Ruxolitinib phosphate.
Salmeterol xinafoate.
Tacrolimus.
Tazarotene.

TABLE 2.—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active Ingredient(s).
Tiotropium bromide.
Tramadol hydrochloride.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved 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. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

V. Electronic Access

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

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27048 Filed 11–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4604]

Per- and Polyfluoroalkyl Substances in Seafood; Request for Information

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information to help fill data gaps that remain regarding per- and polyfluoroalkyl substances (PFAS) in seafood. The purpose of this request is to help increase our understanding of the potential for PFAS exposure from seafood. We intend to use the information submitted in response to this request to help inform future activities to reduce dietary exposure to PFAS that may pose a health concern.

DATES: Either electronic or written comments on the notice must be submitted by February 18, 2025.

ADDRESSES: You may submit comments and information 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 February 18, 2025. 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–2024–N–4604 for ''Per- and Polyfluoroalkyl Substances in Seafood; Request for Information.'' 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.'' We will review this copy, including the claimed confidential information, in our 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: Stacey Wiggins, Office of Dairy and Seafood Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1470; or Alexandra Beliveau or Jessica Ritsick, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

A. PFAS in Food, Generally

PFAS are a diverse group of thousands of synthetic chemicals—including perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid, perfluorononanoic acid, perfluorohexane sulfonic acid, and perfluorodecanoic acid—that are used in a wide range of consumer and industrial products. PFAS do not easily break down, and some types have been shown to accumulate in the environment and in our bodies. Exposure to certain types of PFAS has been linked to serious health effects, including hepatic, cardiovascular, immune, and developmental effects (Refs. 1 through 4).

FDA has developed validated methods for testing for certain PFAS at very low levels (*i.e.,* in the parts per trillion) in increasingly diverse types of foods (Ref. 5). We select specific PFAS for testing based on, for example, information from the scientific literature, the expected PFAS uptake in foods, and the availability of chemical standards to accurately detect and identify the presence of PFAS.

As with other chemical contaminants for which there are no established action levels or tolerances, FDA evaluates PFAS in food on a case-by-case basis. When we detect PFAS in food, we may conduct a human health assessment to evaluate whether the levels detected present a possible human health concern. We consider the level of the contaminant in the specific food, consumption patterns for that specific food in various sectors of the population (by age), and current toxicological data for the PFAS chemical(s) detected to determine whether the concentration of PFAS found in the food poses a health concern (see Ref. 5 for additional information on our approach to human health assessments, generally).

Addressing potential effects of Americans' PFAS exposure is a national priority and is coordinated across several Federal Agencies. Through these interagency collaborations, we are working to identify routes of PFAS exposure, understand associated health risks, and reduce the public's dietary exposure to PFAS that may pose health concern. FDA is a part of the Council on Environmental Quality-led Interagency Policy Committee on PFAS, which is tasked with coordinating the Federal response to PFAS contamination in the environment and in products. Additionally, FDA also participates in an interagency Strategy Team on PFAS, focused on research and development.

B. PFAS in Seafood

For purposes of this document, we use the term ''seafood'' to refer to fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (*e.g.,* alligator) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption, which is consistent with our definition of ''fish'' under 21 CFR 123.3(d). Since 2019, we have been utilizing samples collected from the Total Diet Study (TDS) to evaluate the presence of PFAS in foods, including seafood. The analysis of TDS samples was a preliminary step in determining whether more targeted or larger surveys of PFAS in foods may be needed. To date, we have analyzed 810 TDS food samples, including samples from 7 regional collections and 1 national collection. PFAS were detected at relatively low levels in 23 out of 810 TDS food samples. Of those 23 food samples with PFAS detected, 19 were seafood samples (Ref. 6). Using human health assessments, we determined that none of the TDS seafood samples had levels of PFAS that would be considered a human health concern. However, FDA's testing indicates that seafood may be at higher risk for environmental PFAS contamination compared to other types of food. This request for information is one way we are working to better understand PFAS contamination in commercial seafood to reduce dietary exposure to PFAS that may pose a health concern.

To expand on the results from the TDS samples and evaluate potential exposure to PFAS from other seafood

types, we collected additional seafood samples for PFAS analysis in 2021 and 2022. The survey targeted the most commonly consumed seafood in the United States and consisted of 81 samples comprised of clams, cod, crab, pollock, salmon, shrimp, tilapia, and canned tuna—most of which were imported to the United States. This work advances our efforts to understand PFAS levels in commercial seafood and is also a part of our comprehensive approach to help ensure the safety of imported seafood, as outlined in the ''Activities for the Safety of Imported Seafood'' report released in March 2023 (Ref. 7). Based on the PFOA concentrations found in canned clams, we concluded that consumption of the canned clams sampled from China were likely a human health concern. Two voluntary recalls of processed clams from China have occurred due to these findings (Refs. 8 and 9).

Because many potential hazards can be introduced at the source—in growing areas, in aquaculture farms, and on fishing vessels—seafood presents a unique challenge and opportunity to prevent contamination. This request for information is an opportunity for interested entities (including the seafood industry, academia, and state and other Federal Agencies) (you) to provide information to address the data gaps that exist. This request is consistent with FDA's efforts to increase our understanding of the potential for PFAS exposure from seafood and to reduce dietary exposure to PFAS that may pose a health concern. The information submitted in response to this request for information will help enhance FDA's knowledge about the types of seafood prone to accumulate PFAS and harvest locations with PFAS contamination, improve our comprehensive understanding of the sources of PFAS in seafood, prioritize our sampling strategies and seafood targets for testing, and inform potential mitigation strategies. Additional information about existing data and information on PFAS in seafood will help us advance our public health mission and further support the current Administration's comprehensive approach to addressing PFAS and advancing clean air, water, and food (Refs. 10 through 12).

II. Request for Information

This request focuses on PFAS in seafood. We request data and information in response to specific questions presented below that fall under the following categories: (1) PFAS concentrations in seafood; (2) PFAS concentrations in the environment; (3) PFAS concentrations in processing water; and (4) mitigation strategies for PFAS in seafood. When responding, please identify the question by its number (*e.g.,* ''1.1'') so that we can associate your response with a specific question. Please be as detailed as possible in your response.

It is important to know whether samples were found to contain detectable PFAS. Information about samples where no PFAS was detected is just as important as samples where PFAS was detected. This information helps identify where PFAS was observed and lets us know that it was undetected, as opposed to simply not sampled.

When reporting PFAS concentrations detected (Questions 1–3), please include information about sample preparations (*e.g.,* individual samples versus composites of subsamples) and analytical methods (*e.g.,* the analytical method(s) used and associated limits of detection, limit of quantitation, and method detection limit (MDL)). Such information provides context and helps enable better interpretation of data (*e.g.,* determining which datasets can be compared to other datasets and what conclusions may be drawn). For example, if analytical methods with high MDLs were used and reported non-detectable concentrations, it is possible that the concentrations may have been detectable if a more sensitive method had been used.

While the questions presented below are aimed at gathering data and information on PFAS in seafood that is most pertinent, we welcome any additional data and information regarding PFAS in seafood that may improve our understanding and advance our public health mission.

1. PFAS Concentrations in Seafood

FDA is interested in identifying which specific seafood types are more prone to PFAS accumulation, as this could help inform future seafood sampling plans. We have been analyzing the most commonly consumed seafood in the United States for PFAS; however, there are many other seafood types for which data are limited. Additionally, we are interested in the harvest locations where the seafood samples were collected. Information about geographical PFAS contamination and harvest areas where seafood may be contaminated with PFAS will help inform potential mitigation strategies.

For each item below, please provide the PFAS concentrations for each type of PFAS detected (including samples where no PFAS was detected), as well as any relevant data (*e.g.,* sample collection date), evidence, or other information to support your response.

1.1 Which types of seafood (*e.g.,* scientific name, acceptable market name, common name) have you tested for PFAS? Please describe the sample (*e.g.,* individual or composite) and provide the number of subsamples used for composite samples. Please answer the following questions for each type of seafood tested, providing any data and evidence to support your response.

1.1.1 Was the seafood sample a commercial seafood product (*i.e.,* was the seafood in or intended for interstate commerce whether collected from harvest areas, processing stages, or at retail)? Or was the seafood sample collected a non-commercial seafood product?

1.1.2 Was the seafood sample harvested from fresh water or salt water? What else is known about the harvest location of the seafood sample? Please provide latitude and longitude of harvest location, if known.

1.1.3 Was the seafood sample raw or processed? If raw, was the sample fresh or frozen? If processed, was the sample frozen, canned, pouched, or other? Was the processed sample cooked, eviscerated, smoked, dried, or other?

1.1.4 Was the seafood sample wild-caught or raised via aquaculture?

1.1.5 If the sample was a commercial seafood product, what was the country of origin on the seafood label? The country of origin label indicates the country where the last substantial transformation to the seafood product was made, which may not be the country where the seafood was harvested (19 U.S.C. 1304(a) and 19 CFR part 134; see also Ref. 13).

1.2 Knowing whether the seafood sample (for commercial or non-commercial seafood) has been tested whole or separated into parts is valuable, particularly for informing potential mitigation strategies (*e.g.,* anatomical parts demonstrated to have higher PFAS concentrations may be removed as a mitigation strategy for the remaining parts to be sold for consumption). For each question below, please provide any relevant data, evidence, or other information to support your response.

1.2.1 How would you characterize the seafood sample that was tested (*e.g.,* whole, muscle, roe, viscera)?

1.2.2 If the seafood was separated into different tissues, which specific tissues were used to measure PFAS concentrations? Why were those specific tissues chosen for testing?

2. PFAS Concentrations in the Environment (*e.g.,* Water and Sediment in Seafood Harvest Areas)

PFAS can enter seafood through environmental contamination. FDA is interested in understanding PFAS sources and concentrations in the environment that impact seafood. Such information can aid in the identification of harvest areas to avoid. Examples of PFAS sources in the environment include water and sediment.

For each item below, please provide the PFAS concentrations for each type of PFAS detected (including samples where no PFAS was detected), as well as any relevant data (*e.g.,* sample collection date), evidence, or other information to support your response.

2.1 In conjunction with testing PFAS concentrations in seafood, please describe any environmental samples (*e.g.,* volume or amount of matrix, individual or composite) you have tested from locations where seafood was grown or harvested, including the number of subsamples used for composite samples. Please provide latitude and longitude of sample location, if known.

2.1.1 What type of environmental sample was collected and analyzed for PFAS (*i.e.,* water, sediment, or another type of sample (*e.g.,* soil, biosolids))? Please provide the date of sample collection, if known.

2.1.2 If water, was the sample fresh water or salt water? What was the depth at which the water sample was collected? What was the salinity of the salt water?

2.1.3 If sediment, was the sample mud, sand, or clay? What was the depth at which the sediment was collected?

2.1.4 If another type of sample, please provide additional information about the sample matrix (*e.g.,* whether the samples were biosolids or soils near the coast).

2.2 If known, please provide any historical data you have about PFAS sources in the sampling locale and any information showing a relationship between PFAS in the environmental samples and PFAS in the seafood samples. Such historical information can help identify whether there are patterns or trends in PFAS contamination that may be useful in predicting potential PFAS contamination in seafood, which could inform mitigation efforts.

2.2.1 Are there any factors specific to this geographic location that play a role in PFAS accumulation? If yes, please elaborate.

2.2.2 Is the PFAS contamination in the geographic location persistent? Please provide the rationale for this conclusion.

2.2.3 What, if anything, has the data shown about the source of the PFAS contamination?

3. PFAS Concentration in Processing Water

PFAS can enter processed seafood through the use of contaminated processing water. FDA would like to know about the occurrence of PFAS contamination in processing water intended for use with seafood. Identification of the source of contaminated water that was intended for use as processing water will help FDA better understand potential and likely routes of PFAS contamination, and may help inform mitigation strategies, such as the need to find alternative source water for food processing. It is also helpful to know if water that was intended for use as processing water was tested but not found to contain detectable concentrations of PFAS.

For each item below, please provide the PFAS concentrations for each type of PFAS detected (including samples where no PFAS was detected), as well as any relevant data (*e.g.,* sample collection date), evidence, or other information to support your response.

3.1 What processing water samples have been tested for PFAS? At what stage of processing was the process water used or intended to be used? Please describe the sample (*e.g.,* individual or composite, volume) and provide the number of subsamples used for composite samples.

3.2 What is the source of the processing water (*e.g.,* municipal, private, well)? If known, please provide any historical data you have about PFAS sources in the sampling locale of the processing water, and any information showing a relationship between PFAS in the processing water samples and seafood samples. Such information can help identify whether patterns or trends are available to aid in mitigation efforts.

4. Mitigation Strategies for PFAS in Seafood

As PFAS are known to accumulate and persist in the environment, it is important to develop mitigation strategies for reducing PFAS contamination in seafood. Examples of mitigation strategies include changing or closing seafood harvest locations if an area is contaminated with PFAS or processing certain tissues of seafood that have been determined to not accumulate PFAS. Understanding the rates of PFAS accumulation and elimination from seafood can help to determine whether natural or controlled reduction strategies may be effective at removing PFAS. FDA is interested to learn about additional mitigation strategies that may be used to reduce or prevent PFAS contamination of seafood. For each item below, please provide any relevant data, evidence, or other information to support your response.

4.1 Please describe the PFAS mitigation strategies that you have used or of which you are aware to reduce PFAS in seafood, including any industry-wide practices. Please provide details regarding, as applicable, testing seafood products and/or processing water for PFAS, changing seafood harvest areas and/or processing water sources based on PFAS concentrations, eviscerating seafood and/or processing different tissues for consumption, or depurating (*i.e.,* storing in controlled conditions to allow for elimination of impurities) PFAS from seafood.

4.1.1 Which mitigation strategies have you determined to be successful at reducing PFAS in seafood? Please provide details about the strategy, including your criteria for determining success and the level to which PFAS was reduced.

4.1.2 What challenges have you encountered regarding mitigation strategies for reducing PFAS contamination in seafood?

4.2 If any seafood growing areas or harvest areas have been found to be contaminated with PFAS, please describe whether the area has been placed in a closed or prohibited status, you have been impacted by growing or harvest areas being placed in a closed status, or you have avoided harvesting in the area. Please describe the contamination event in as much detail as possible (*e.g.,* PFAS concentration, location with latitude and longitude if known, length of closure or avoidance).

4.3 To what degree is PFAS in seafood testing being incorporated into Seafood Hazard Analysis Critical Control Point (HACCP) plans? If PFAS was detected in seafood or processing water, was PFAS added to HACCP plans? Please provide details, such as what critical limit is being considered.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Agency for Toxic Substances and Disease Registry, ''Toxicological Profile for Perfluoroalkyls.'' Accessed June 14, 2024. Available at: *https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.*
2. U.S. Environmental Protection Agency, ''Human Health Toxicity Assessment for PFBS.'' Accessed June 14, 2024. Available at: *https://www.epa.gov/chemical-research/learn-about-human-health-toxicity-assessment-pfbs.*
3. U.S. Environmental Protection Agency, ''Human Health Toxicity Assessments for GenX Chemicals.'' Accessed June 14, 2024. Available at: *https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.*
4. U.S. Environmental Protection Agency, ''Final IRIS Assessment of Perfluorobutanoic Acid (PFBA) and Related Salts.'' Accessed June 14, 2024. Available at: *https://www.epa.gov/newsreleases/epa-publishes-iris-handbook-and-final-iris-assessment-perfluorobutanoic-acid-pfba-and.*
5. U.S. Food and Drug Administration, ''Testing Food for PFAS and Assessing Dietary Exposure.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure.*
6. U.S. Food and Drug Administration, ''Analytical Results of Testing Food for PFAS from Environmental Contamination.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/food/process-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination.*
7. U.S. Food and Drug Administration, ''Activities for the Safety of Imported Seafood, February 2023.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/media/165447/download.*
8. U.S. Food and Drug Administration, ''FDA Shares Results on PFAS Testing in Seafood, July 15, 2022.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/food/cfsan-constituent-updates/fda-shares-results-pfas-testing-seafood.*
9. U.S. Food and Drug Administration, ''Crown Prince, Inc. Issues Voluntary Recall of Smoked Baby Clams in Olive Oil Due to the Presence of Detectable Levels of PFAS Chemicals.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/crown-prince-inc-issues-voluntary-recall-smoked-baby-clams-olive-oil-due-presence-detectable-levels.*
10. The White House, ''Fact Sheet: Biden-Harris Administration Launches Plan to Combat PFAS Pollution, October 2021.'' Accessed June 14, 2024. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/18/fact-sheet-biden-harris-administration-launches-plan-to-combat-pfas-pollution/.*
11. The White House, ''Fact Sheet: Biden-Harris Administration Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans, June 2022.'' Accessed June 14, 2024. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/15/fact-sheet-biden-harris-administration-combatting-pfas-pollution-to-safeguard-clean-drinking-water-for-all-americans/.*
12. The White House, ''Fact Sheet: Biden-Harris Administration Takes New Action to Protect Communities from PFAS Pollution, March 2023.'' Accessed June 14, 2024. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/14/fact-sheet-biden-harris-administration-takes-new-action-to-protect-communities-from-pfas-pollution/.*
13. U.S. Food and Drug Administration, ''CPG Sec. 560.200 Country of Origin Labeling.'' Accessed June 14, 2024. Available at: *https://www.fda.gov/media/71994/download.*

Dated: November 12, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27070 Filed 11–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Office of the Commissioner (OC), Office of Digital Transformation (ODT) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on September 20, 2024.

FOR FURTHER INFORMATION CONTACT: William Tootle, Director, Office of Budget; 10903 New Hampshire Avenue, WO–2, #3313, Silver Spring, MD 20990.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect FDA, OC's ODT.

The changes to ODT's organizational structure consolidate similar functions and resources across multiple areas and align the organizational structure with federal and industry standards. This will create a more agile organization, improve resource management, enhance customer service, and better align the name of organizational components with current functions. The reorganization will maintain a reasonable span of control and clear and appropriate lines of authority and responsibilities between organizations. This will also ensure optimal resource utilization and leveraging of existing staff talent and will allow ODT more efficiency and effectiveness in the advancement of continuous improvement efforts.

DCAD. ORGANIZATION: ODT is headed by the Chief Information Officer and includes:

Office of Digital Transformation (DCAD)
Office of Information Management and Technology (DCADA)
Enterprise Architecture Staff (DCADA2)
Office of Technology and Delivery (DCADAA)
Division of Infrastructure Services (DCADAAA)
Network Services Support Staff (DCADAAA10)
Systems Operations Support Staff (DCADAAA11)
Operations and Planning Staff (DCADAAA12)
Data Center Facilities Branch (DCADAAA13)
Quality Assurance Branch (DCADAAA14)
Network Communications Branch (DCADAAA15)
Server Operations Services Branch (DCADAAA16)
Enterprise Management Operations Branch (DCADAAA17)
Cloud Operations Branch (DCADAAA18)
Division of Application Services (DCADAAB)
Operations Support Staff (DCADAAB10)
Enterprise Business and Post-Market Staff (DCADAAB11)
Scientific Support Staff (DCADAAB12)
Human Food Support Branch (DCADAAB13)
Regulatory Science Support Branch (DCADAAB14)
Compliance and Enforcement Branch (DCADAAB15)
Application Services Support Branch (DCADAAB16)
Platform Management Support Branch (DCADAAB17)
Digital Solutions Partners Branch (DCADAAB18)
Business Intelligence Data Branch (DCADAAB19)
Products Review and Approval Branch (DCADAAB20)
Digital Solution Delivery Branch (DCADAAB21)
Registration Listing Services Branch (DCADAAB22)
User Fee Support Branch (DCADAAB23)
Division of Engineering (DCADAAD)