

to comments and suggestions submitted within 60 days of this publication.

*Authority:* 42 U.S.C. 653A(b)(1)(A) and (B); 42 U.S.C. 653A(g)(2)(A); 26 U.S.C. 3304(a)(16)(B); 42 U.S.C. 503(h)(1)(A); and 42 U.S.C. 653A(g)(2)(B).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Children’s Bureau National Youth in Transition Database (NYTD) (OMB #0970-0340)**

**AGENCY:** Children’s Bureau, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting a 3-year extension of the National Youth in Transition Database (NYTD) Youth Services Report and Youth Outcomes Survey Data Collection (OMB #0970-0340, expiration date 03/31/2022). There are no changes requested to the form.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** You can obtain copies of the proposed collection of information and submit comments by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The Foster Care Independence Act of 1999 (42 U.S.C. 1305 *et seq.*) as amended by Public Law 106-169 requires state child welfare agencies to collect and report to the ACF

Children’s Bureau data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing NYTD, listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for states to meet the law’s requirements. Additionally, the Family First Prevention Services Act of 2017 (H.R. 253) further outlines the expectation of the collection and reporting of data and outcomes regarding youth who are in receipt of independent living services. ACF uses the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and potentially to evaluate state performance with regard to those outcomes consistent with the law’s mandate.

*Respondents:* State agencies that administer the Chafee Foster Care Program for Successful Transition to Adulthood (Chafee program) and youth served by these agencies.

**ANNUAL BURDEN ESTIMATES FOR 2022-2024**

Information collection title	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours for 2022-24	Annual burden hours
State Data File .....	52	2	3916	407,264	135,755
Youth Outcomes Survey .....	47,000	1	.5	23,500	7,833
Estimated Annual Burden Total .....					143,588

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* NYTD is authorized by Public Law 106-169, enacted December 14, 1999. This public law establishes the John H. Chafee Foster Care Independence Program, now known as Chafee program, at section 477 of the

Social Security Act. NYTD data is collected pursuant to 45 CFR 1356.80.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2021-28058 Filed 12-23-21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-D-0367]

**Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-Forming Fish and Fishery Products—Decomposition and Histamine; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft

Compliance Policy Guide entitled “Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine.” The draft guidance, when finalized, will replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation.

**DATES:** Submit either electronic or written comments on the draft guidance by February 25, 2022 to ensure that we consider your comment on the draft guidance before we begin 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-0367 for "Sec. 540.525 Scombrototoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24)." 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." 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.

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 Division of Seafood Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

#### FOR FURTHER INFORMATION CONTACT:

Steven Bloodgood, Division of Seafood Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5316, email: [steven.bloodgood@fda.hhs.gov](mailto:steven.bloodgood@fda.hhs.gov); or Jessica Larkin, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a draft Compliance Policy Guide (CPG) entitled "Sec. 540.525 Scombrototoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24)." This draft

CPG would update and replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to scombrototoxin (histamine) formation. The draft CPG would revise FDA regulatory action guidance for sensory analysis and/or histamine levels in scombrototoxin-forming fish and fishery products.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 21, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1252]

### Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Proposal To Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of three new drug applications (NDAs) and is announcing an opportunity for the NDA holders to