practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on SPA. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 collections of information referred to in the guidance entitled ''Special Protocol Assessment'' have been approved under OMB control number 0910–0470. The collections of information for Form FDA 1571 have been approved under OMB control number 0910–0014.

III. Electronic Access

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

Dated: April 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07871 Filed 4–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1189]

Highly Concentrated Caffeine in Dietary Supplements; Guidance for Industry; 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 guidance for industry, ''Highly Concentrated Caffeine in Dietary Supplements.'' FDA considers some dietary supplements that consist of only or primarily pure or highly concentrated caffeine to be adulterated. FDA is issuing this document to provide guidance to firms that manufacture, market, or distribute dietary supplement products that contain pure or highly concentrated caffeine, or are considering doing so. This guidance should help such parties determine whether their products are or would be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to help them understand how to reduce the likelihood that their products will be considered adulterated.

DATES: The announcement of the guidance is published in the **Federal Register** on April 16, 2018.

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–2018–D–1189 for ''Highly Concentrated Caffeine in Dietary Supplements; Guidance for Industry; Availability.'' 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.'' 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.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 guidance to Office of Dietary Supplement Programs, 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

requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sibyl Swift, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1455.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Highly Concentrated Caffeine in Dietary Supplements.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation 21 CFR 10.115. In accordance with 21 CFR § 10.115(g)(2), we are issuing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate in light of the threat to the public health that is posed by pure and highly concentrated caffeine products, which have been linked to several deaths in recent years. Although this guidance is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

In this guidance, we are announcing that we consider some dietary supplements containing high concentrations of caffeine to be adulterated and informing industry about characteristics that are likely to lead to products being considered adulterated. A dietary supplement is adulterated under section 402(f)(1)(A) of the FD&C Act (21 U.S.C. 342(f)(1)(A)) if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling or, if no conditions for use are suggested or recommended, under ordinary conditions of use. In recent years, we have seen the emergence of powdered and liquid dietary supplement products containing high concentrations of caffeine marketed directly to consumers. These products are often sold in bulk containers with hundreds or thousands of servings in the container, and even a small dose can be toxic or deadly. The consumer is required to measure out a small, precise serving from what is often a potentially lethal amount of product. These products pose a significant or unreasonable risk of illness or injury.

When formulated appropriately, caffeine can be an ingredient in a dietary supplement that does not present a significant or unreasonable risk of illness or injury. The guidance provides suggestions on how manufacturers can formulate safer dietary supplements containing caffeine that do not present a significant or unreasonable risk of illness or injury.

The guidance represents our current thinking on dietary supplements containing high concentrations of caffeine. 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. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.*

Dated: April 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07836 Filed 4–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that on April 2, 2018, the Department of Health and Human Services (HHS) Debarring Official, on behalf of the Secretary of HHS, issued a final notice of debarment based on the findings of research misconduct made by the Office of Research Integrity (ORI) against H.M. Krishna Murthy, Ph.D., former Research Associate Professor, Department of Vision Sciences, University of Alabama at Birmingham (UAB).

Dr. Murthy engaged in research misconduct in research supported by U.S. Public Health Service (PHS) grants, specifically National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI051615, R01 AI032078, and R01 AI045623; National Heart, Lung, and Blood Institute (NHLBI), NIH, grants P01 HL034343 and R01 HL064272; and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK046900. The administrative actions, including ten (10) years of debarment, were implemented beginning on April 2, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that HHS has taken final action in the following case:

H.M. Krishna Murthy, Ph.D., University of Alabama at Birmingham: Based on evidence and findings of an investigation conducted by UAB, ORI's review of UAB's investigation, and additional evidence obtained and analysis conducted by ORI in its oversight review of UAB's investigation, ORI found that Dr. H.M. Krishna Murthy (Respondent), former Research Associate Professor, Department of Vision Sciences, UAB, committed research misconduct in research supported by PHS grants, specifically NIAID, NIH, grants R01 AI051615, R01 AI032078, and R01 AI045623; NHLBI, NIH, grants P01 HL034343 and R01 HL064272; and NIDDK, NIH, grant R01 DK046900.

Falsified and/or fabricated research was reported in:

- *Nature* 444:221–225, 2006 (hereafter referred to as ''*Nature* 2006''); retracted in: *Nature* 532:268, 2016 April 14
- *J. Biol. Chem.* 274:5573–5580, 1999 (hereafter referred to as ''*J. Biol. Chem.* 1999''); retracted in: *J. Biol. Chem.* 284:34468, 2009
- *Proc. Natl. Acad. Sci. USA* 101:8924–8929, 2004 (hereafter referred to as ''*PNAS* 2004''); Editorial Expression of Concern in: *PNAS* 107:6551, 2010 April 6
- *Biochem.* 44:10757–10765, 2005 (hereafter referred to as ''*Biochem.* 2005'')
- *Proc. Natl. Acad. Sci. USA* 103:2126–2131, 2006 (hereafter referred to as ''*PNAS* 2006''); Editorial Expression of Concern in: *PNAS* 107:6551, 2010 April 6
- *Acta Cryst.* D55:1971–1977, 1999 (hereafter referred to as ''*Acta Cryst.* 1999''); retracted in: *Acta Cryst.* D66:222, 2010
- *J. Mol. Biol.* 301:759–767, 2000 (hereafter referred to as ''*J. Mol. Biol.* 2000''); retracted in: *J. Mol. Biol.* 397:1119, 2010
- *Cell* 104:301–311, 2001 (hereafter referred to as ''*Cell* 2001'')
- *Biochem.* 41:11681–11691, 2002 (hereafter referred to as ''*Biochem.* 2002'')
- Protein Data Bank (PDB) identification codes 2HR0, 1BEF, 1RID, 1Y8E, 2A01, 1CMW, 2QID, 1DF9, 1G40, 1G44, 2OU1, and 1L6L (the PDB is funded in part by NIH)

Falsified and/or fabricated research results also were referenced in the following PHS grant applications:

- 1 R21 AI056224–01 submitted to NIAID, NIH
- 1 R01 AI064509–01 submitted to NIAID, NIH
- 1 R01 AI64509–01A1 submitted to NIAID, NIH
- 1 R01 AI051615–01A1 submitted to NIAID, NIH
- 1 R03 TW006840–01 submitted to Fogarty International Center (FIC), NIH