

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) Debarment 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

ORI found by a preponderance of the evidence that Respondent intentionally, knowingly, or recklessly engaged in research misconduct by falsifying and/or fabricating X-ray crystallographic data for eleven (11) protein structures and falsely reporting them as experimentally derived from X-ray diffraction experiments in nine (9) publications and in twelve (12) deposits in the PDB. ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated the PDB coordinate files deposited for all of the eleven (11) structures (PDB entries 2HR0, 1BEF, 1RID, 1Y8E, 2A01, 1CMW, 1G40, 1G44, 2OU1, 1L6L, 2QID, and 1DF9) and the X-ray diffraction data (structure factors) corresponding to six (6) of the eleven (11) structures (PDB entries 2HR0, 1BEF, 1RID, 1Y8E, 2A01, and 1CMW).

Specifically, Respondent falsified and/or fabricated:

- The protein crystal structure of complement component C3b reported in *Nature* 2006 and the corresponding structure factors and coordinate file deposited in the PDB for entry 2HR0
- the protein crystal structure of dengue virus NS3 serine protease reported in *J. Biol. Chem.* 1999 and the corresponding structure factors and coordinate file deposited in the PDB for entry 1BEF
- the protein crystal structure of vaccinia virus complement control protein (VCP) in complex with heparin reported in *PNAS* 2004 and the corresponding structure factors and coordinate file deposited in the PDB for entry 1RID
- the protein crystal structure of VCP in complex with suramin (VCP-suramin) reported in *Biochem.* 2005 and the corresponding structure factors and coordinate file deposited in the PDB for entry 1Y8E
- the protein crystal structure of apolipoprotein A-I reported in *PNAS* 2006 and the corresponding structure factors and coordinate file deposited in the PDB for entry 2A01
- the protein crystal structure of Taq DNA polymerase reported in *Acta Cryst.* 1999 and the corresponding structure factors and coordinate file deposited in the PDB for entry 1CMW
- the protein crystal structure of VCP crystal form I reported in *Cell* 2001 and the corresponding coordinate files deposited in the PDB for entry 1G40
- the protein crystal structure of VCP crystal form II reported in *Cell* 2001 and the corresponding coordinate file deposited in the PDB for entry 1G44
- the protein crystal structure of apolipoprotein A-II reported in

*Biochem.* 2002 and the corresponding coordinate file deposited in the PDB for entry 2OU1

- the protein crystal structure of apolipoprotein A-II in complex with  $\beta$ -octyl glucoside reported in *Biochem.* 2002 and the corresponding coordinate file deposited in the PDB for entry 1L6L
- the protein crystal structure of dengue virus NS3 protease in complex with a Bowman-Birk inhibitor reported in *J. Mol. Biol.* 2000 and the corresponding coordinate files deposited in the PDB for entries 2QID and 1DF9

ORI issued a charge letter enumerating the above findings of research misconduct and proposing HHS administrative actions. Respondent subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. ORI filed a motion for summary judgment, which Respondent opposed. On January 19, 2018, the ALJ issued a recommended decision to the Acting Assistant Secretary for Health (ASH) granting summary judgment in favor of ORI and sustaining ORI's proposal to impose a ten-year debarment and a ten-year ban on PHS advisory services against Respondent as well as correction of Respondent's research record. The Acting ASH served a copy of the ALJ's recommended decision on the HHS Debarring Official pursuant to 42 CFR 93.523(c), and the decision constituted the findings of fact to the HHS Debarring Official in accordance with 2 CFR 180.845(c). On April 2, 2018, the HHS Debarring Official issued a final notice of debarment to begin on April 2, 2018, and end on April 1, 2028. Thus, the research misconduct findings set forth above became effective, and the following administrative actions have been implemented, beginning on April 2, 2018:

(1) Dr. Murthy is debarred for a period of ten (10) years from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government, referred to as "covered transactions," pursuant to HHS' Implementation (2 CFR part 376) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR part 180);

(2) Dr. Murthy is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of ten (10) years; and

(3) ORI will send a notice to the pertinent journals of the following publications that require retraction or correction and to the PDB for the following entries that require obsolescence, in accordance with 42 CFR 93.407(a)(1) and 93.411(b):

- Cell* 104:301–311, 2001
- Biochem.* 41:11681–11691, 2002
- Proc. Natl. Acad. Sci. USA* 101:8924–8929, 2004
- Biochem.* 44:10757–10765, 2005
- Proc. Natl. Acad. Sci. USA* 103:2126–2131, 2006
- PDB entries 1RID, 1Y8E, 2A01, 1G40, 1G44, 2OU1, and 1L6L

Wanda K. Jones,

Interim Director, Office of Research Integrity.

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BILLING CODE 4150–31–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Indian Health Professions Preparatory, Indian Health Professions Pre-Graduate and Indian; Health Professions Scholarship Programs

Announcement Type: Initial

CFDA Numbers: 93.971, 93.123, and 93.972

#### Key Dates

Application Deadline Date: April 13, 2018, 7:00 p.m. Eastern for continuing students

Application Deadline Date: April 13, 2018, 7:00 p.m. Eastern for new students

Application Review Date: May 7–25, 2018

Continuation Award Notification

Deadline Date: June 5, 2018

New Award Notification Deadline Date: July 15, 2018

Award Start Date: August 1, 2018

Acceptance/Decline of Awards Deadline Date: August 15, 2018

#### I. Funding Opportunity Description

The Indian Health Service (IHS) is committed to encouraging American Indians and Alaska Natives to enter the health professions and to assuring the availability of Indian health professionals to serve Indians. The IHS is committed to the recruitment of students for the following programs:

- *The Indian Health Professions Preparatory Scholarship (Preparatory Scholarship)* authorized by Section 103 of the Indian Health Care Improvement Act, Public Law 94–437 (1976), as amended (IHCIA), codified at 25 U.S.C. 1613(b)(1).

- *The Indian Health Professions Pre-graduate Scholarship (Pre-graduate*