

Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology were accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude herself 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 FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011-33650 Filed 12-30-11; 8:45 am]

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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 the Office of Research Integrity (ORI) has taken final action in the following case:

Mahesh Visvanathan, Ph.D., Kansas University: Based on an inquiry conducted and written admission obtained by Kansas University (KU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mahesh Visvanathan, Research Assistant Professor in the K-INBRE¹ Bioinformatics Core Facility, KU, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically the INBRE program of the National Center for Research Resources (NCRR), National Institutes of Health (NIH), grant P20 RR016475.

Specifically, ORI found that Respondent engaged in research

misconduct by intentionally and knowingly plagiarizing large amounts of text from other writers' published papers without attribution or citation in the following three (3) papers and one (1) abstract. The specific published documents as well as the relevant source documents are:

- Visvanathan, M., Adagarla, B., Lushington, G., Sittampalam, S., *Proceedings of the 2009 International Joint Conference on Bioinformatics, Systems, Biology and Intelligent Computing*, 2009, 494-497. Greater than half (50%) of the total text was obtained from (1) Yang, C.-S., Chuang, L.-Y., Ke, C.-H., Yang, C.-H., *International Journal of Computer Science, International Association of Engineers*, August 2008 35(3), (2) Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176- W181, and (3) Chuang, L.-Y., Yang, C.-H., Tu, C.-J., Yang, C.-H., *Proceedings of the Joint Conference on Information Sciences*, Atlantis Press, October 2006.

Retracted: Retracted administratively by IEEE on Jan 5, 2011 http://ieeexplore.ieee.org/xpl/freeabs_all.jsp?arnumber=5260432.

- Vijayan, A.; Skariah, B. E., Nair, B.; Lushington, G., Subramanian, S., Visvanathan, M., *Proceedings of the IEEE International Conference on Bioinformatics and Biomedicine Workshop*, 2009, BIBMW2009, 267-271. Approximately 15% of the text was plagiarized from Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176-W181.

Retracted: Retracted administratively by IEEE on Jan 5, 2011 <http://www.computer.org/portal/web/csdl/doi/10.1109/BIBMW.2009.5332106>.

- Visvanathan, M., Netzer, M., Seger, M., Adagarla, B. S., Baumgartner, C., Sittampalam, S., Lushington, G., *International Journal of Computational Biology and Drug Design*, 2009, 2,236-251. A complete paragraph of the text was plagiarized from Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176- W181.

- Adagarla, B., Lushington, G., Visvanathan, M., ISMB International Conference, January 2009; the entire abstract for this poster was obtained by plagiarizing text from Pihur, V., Datta, S., Datta S., *Genomics*, 2003, 92:400-403.

Dr. Visvanathan has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on December 20, 2011:

(1) To have any PHS-supported research supervised; ORI acknowledges that Respondent's research is currently being supervised by KU; Respondent

shall ensure that a plan for supervision of his PHS-related duties is submitted to ORI for approval either within two weeks of this Agreement becoming final or prior to receiving or applying for PHS funds if such support is not current at the time this Agreement is completed; the supervision plan must be designed to ensure the scientific integrity of his research contribution; because of the ongoing review of Respondent's research by KU, ORI will only require a summary report on the first and second anniversary of the Agreement detailing how KU has ensured that Respondent's research and language in PHS grant applications and reports of PHS-supported research have been verified to be his own and accurately reported; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) That this annual summary, provided by any institution employing him, shall provide assurance that each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent was involved, was based on actual experiments or was otherwise legitimately derived, that the data, procedures, and methodology were accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions was his own or properly cited the source of copied language and ideas; and

(3) To exclude himself 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 FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. (240) 453-8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011-33651 Filed 12-30-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0916]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Device Classification Product Codes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

¹ K-INBRE: The Kansas IDeA Network of Biomedical Research Excellence, which is a consortium of a number of schools and centers in Kansas.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Device Classification Product Codes.” The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices regulated by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This document describes how classification product codes are used in a variety of FDA program areas to regulate and track medical devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 2, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Medical Device Classification Product Codes” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at (301) 847–8149. The draft guidance may also be obtained by mail by calling CBER at (800) 835–4709 or (301) 827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 66, Rm. 1644, Silver Spring, MD 20993–0002, (301) 796–6559; and

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, (301) 827–6210.

I. Background

Since the May 28, 1976, Medical Device Amendments were passed, the Classification Regulation Panels (parts 862 through 892 (21 CFR parts 862 through 892)) have been the basis for the CDRH’s Classification Product Code structure and organization. These 16 Panels have largely been the driving force for CDRH’s internal organizational structure as well. Relying on the Classification Regulation Panels structure, CDRH created classification product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking and easy reference of predicate device types.

Classification product codes are a method of classifying medical devices. Medical device product codes consist of a three-letter combination, which associates a device’s type with a product classification. Classification product codes and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation.

The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices in a variety of FDA program areas to regulate and track medical devices. This document is limited to medical devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and does not discuss classification products codes used to regulate non-medical electronic radiation emitting products.

The scope of the guidance document includes devices described in the existing classification under parts 862 through 892. It also describes how classification product codes are used for CBER regulated devices, which currently do not fall within this existing classification. This guidance may also be applicable to future devices. It also covers unclassified devices and devices not yet classified.

II. Significance of Guidance

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 Agency’s current thinking

on medical device classification product codes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive “Medical Device Classification Product Codes,” you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a hard copy. Please use the document number 1774 to identify the guidance you are requesting.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–33686 Filed 12–30–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.