



U.S. OFFICE OF SPECIAL COUNSEL

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The Special Counsel

February 7, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: OSC File No. DI-19-0931
Referral for Investigation-5 U.S.C. §1213(c)

Dear Mr. Secretary:

I am referring to you for investigation a whistleblower disclosure that officials at the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Rockville, Maryland, engaged in conduct that may constitute a violation of law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health. A report of your investigation on these allegations and any related matters is due to the Office of Special Counsel (OSC) on April 8, 2019.

██████████, a consumer safety officer, who consented to the release of his name, disclosed that Team Biologics manager ██████████ improperly downgraded several inspection conclusion reports without filing reclassification memoranda, as required in FDA's Regulatory Procedures Manual. The allegations to be investigated include:

- The inspection conclusion report for the 2017 National Genetics Institute inspection (FEI 3002082450) was designated as Official Action Indicated (OAI) and was subsequently reclassified as Voluntary Action Indicated (VAI) without a reclassification memorandum;
- The inspection conclusion report for the 2018 Baxalta US, Inc. inspection (FEI 3003282293) determined that the case should be considered OAI, with a recommended Untitled Letter. This was later downgraded to VAI without a reclassification memorandum;
- The inspection conclusion report for the 2018 CSL Behrin GmbH inspection was entered as OAI and subsequently downgraded to VAI without a reclassification memorandum; and
- During the 2018 inspection of Merck Sharp and Dohme (FEI 3006525584), ██████████ discovered evidence that the company was intentionally destroying evidence of possible violations, which was confirmed by a

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Confidential Informant. [REDACTED] asserted that FDA procedures for responding to the receipt of this information were not followed.

[REDACTED] explained that these inspections uncovered serious potential safety issues with each manufacturer. He also noted that the reduction to VAI from OAI would result in a lower level of scrutiny applied to future site inspections and could therefore potentially compromise public health.

Pursuant to my authority under 5 U.S.C. § 1213(c), I have concluded that there is a substantial likelihood that the information provided to OSC discloses a violation of law, rule, or regulation, gross mismanagement, and a substantial and specific danger to public health. Please note that specific allegations and references to specific violations of law, rule, or regulation are not intended to be exclusive. If, in the course of your investigation, you discover additional violations, please include your findings on these additional matters in the report to OSC. As previously noted, your agency must conduct an investigation of these matters and produce a report, which must be reviewed and signed by you. Per statutory requirements, I will review the report for sufficiency and reasonableness before sending copies of the agency report, along with the whistleblower's comments and any comments or recommendations I may have, to the President and congressional oversight committees and making these documents publicly available.

Additional important requirements and guidance on the agency report are included in the attached Appendix, which can also be accessed at <https://osc.gov/Pages/DOW.aspx>. If your investigators have questions regarding the statutory process or the report required under section 1213, please contact Catherine A. McMullen, Chief, Disclosure Unit, at (202) 804-7088 for assistance. I am also available for any questions you may have.

Sincerely,



Henry J. Kerner
Special Counsel

Enclosure

cc: The Honorable Daniel R. Levinson, Inspector General

APPENDIX
AGENCY REPORTS UNDER 5 U.S.C. § 1213

GUIDANCE ON 1213 REPORT

- OSC requires that your investigators interview the whistleblower at the beginning of the agency investigation when the whistleblower consents to the disclosure of his or her name.
- Should the agency head delegate the authority to review and sign the report, the delegation must be specifically stated and include the authority to take the actions necessary under 5 U.S.C. § 1213(d)(5).
- OSC will consider extension requests in 60-day increments when an agency evidences that it is conducting a good faith investigation that will require more time to complete.
- Identify agency employees by position title in the report and attach a key identifying the employees by both name and position. The key identifying employees will be used by OSC in its review and evaluation of the report. OSC will place the report without the employee identification key in its public file.
- Do not include in the report personally identifiable information, such as social security numbers, home addresses and telephone numbers, personal e-mails, dates and places of birth, and personal financial information.
- Include information about actual or projected financial savings as a result of the investigation as well as any policy changes related to the financial savings.
- Reports previously provided to OSC may be reviewed through OSC's public file, which is available here: <https://osc.gov/Pages/Resources-PublicFiles.aspx>. Please refer to our file number in any correspondence on this matter.

RETALIATION AGAINST WHISTLEBLOWERS

In some cases, whistleblowers who have made disclosures to OSC that are referred for investigation pursuant to 5 U.S.C. § 1213 also allege retaliation for whistleblowing once the agency is on notice of their allegations. The Special Counsel strongly recommends the agency take all appropriate measures to protect individuals from retaliation and other prohibited personnel practices.

EXCEPTIONS TO PUBLIC FILE REQUIREMENT

OSC will place a copy of the agency report in its public file unless it is classified or prohibited from release by law or by Executive Order requiring that information be kept secret in the interest of national defense or the conduct of foreign affairs. 5 U.S.C. § 1219(a).

EVIDENCE OF CRIMINAL CONDUCT

If the agency discovers evidence of a criminal violation during the course of its investigation and refers the evidence to the Attorney General, the agency must notify the Office of Personnel Management and the Office of Management and Budget. 5 U.S.C. § 1213(f). In such cases, the agency must still submit its report to OSC, but OSC must not share the report with the whistleblower or make it publicly available. See 5 U.S.C. §§ 1213(f), 1219(a)(1).