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MEMORANDUM

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Date: April 21, 2016

RE: OHSA Finalizes FSMA Whistleblower Protection Regulations

On April 18, 2016, the Department of Labor's Occupational Safety and Health Administration (OSHA) promulgated a final rule 1/ that finalizes with minor changes an interim final rule (IFR) published in February 2014. 2/ The final rule implements the employee protection (i.e., "whistleblower") provision of the FDA Food Safety Modernization Act (FSMA). It is procedural in nature, establishing administrative procedures for handling whistleblower retaliation complaints. FSMA's whistleblower protections took effect immediately upon the law's enactment in January 2011 and the IFR became effective upon publication in February 2014. The final rule also takes effect immediately. This memorandum summarizes the statutory whistleblower protections and OSHA's final rule.

Whistleblower Protections Established By FSMA

Section 402 of FSMA added Section 1012 to the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 399d) regarding employee protections. Although the Food and Drug Administration (FDA) generally administers the FFDCA, the Secretary of Labor is responsible for enforcing the employee protection provision in FFDCA Section 1012. This provision prohibits all entities engaged in the manufacture, processing, packing, transportation, distribution, reception, holding, or importation of food from discharging or otherwise discriminating against employees because they:

- Provided (or are about to provide) information to their employer, the federal government, or a state attorney general relating to any violation (or any act the employee believes to be a violation) of any provision of the FFDCA, including FDA's implementing regulations;
- Testified (or are about to testify) in a proceeding concerning such violation;
- Assisted or participated (or are about to assist or participate) in such a proceeding; or
- Objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be a violation of the FFDCA or an implementing regulation.

Overview of OSHA's Final Rule

OSHA's 2014 IFR established the procedural framework to be followed under FFDCA Section 1012 when an employee alleges that whistleblower retaliation has occurred. Although the IFR became effective upon publication in February 2014, OSHA accepted comments on the IFR through April

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1/ 81 Fed. Reg. 22530 (Apr. 18, 2016).

2/ 79 Fed. Reg. 8619 (Feb. 13, 2014); *see* Hogan Lovells memorandum, *OSHA Issues FSMA Whistleblower Protection Regulations* (Feb. 14, 2014).

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2014. Only two organizations submitted comments responsive to the IFR. As a result, the final rule largely reflects the IFR, with only minor changes to the provisions addressing OSHA investigations. 3/

The regulation establishes the following procedures, which are intended to be consistent with other employee whistleblower protections that OSHA administers under other statutes:

- **Complaint and Investigation.** A retaliation complaint must be filed within **180 days** of the adverse action (e.g. termination or discipline) against the employee. OSHA will notify the employer of the filing of the complaint and the allegations and evidence.
    - The employer may, within **20 days** after receipt of the notification, submit a written statement and evidence, and request a meeting with OSHA.
    - The final rule clarifies OSHA's policy that the agency will request that each party provide the other with a copy of all submissions to OSHA and, if they do not, OSHA will provide the submissions. Each party will have an opportunity to respond to the other party's submissions.
    - OSHA will dismiss the complaint:
        - (1) if the employee fails to make a *prima facie* showing that protected activity was a contributing factor in the adverse action (e.g., the employee was terminated promptly after engaging in protected activity), or
        - (2) if the employer demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of the employee's protected activity.
    - If OSHA has reasonable cause to believe that the employer has illegally retaliated, OSHA will again contact the employer, give notice of the relevant evidence, and give the employer **10 business days** to submit a written response, meet with investigators, and present arguments.

- **Written Findings.** Within **60 days** of the filing of the complaint, OSHA will issue written findings. If OSHA believes a violation has occurred, it will issue a preliminary order providing relief to the employee, which may require, *inter alia*, (1) affirmative action to abate the violation; (2) reinstatement of the employee; (3) monetary compensation to the employee; and (4) attorney's fees.

- **Objections.** A party may file objections within **30 days** of receipt of the findings. This will stay all provisions of the preliminary order, except that in most cases, it will not stay an order requiring preliminary reinstatement. After receipt of the objection, the case will be assigned to an **Administrative Law Judge** ("ALJ"). The ALJ will inform the parties by mail of the location and date of the hearing, which is to be scheduled to commence "expeditiously."

- **ALJ Hearing.** ALJ hearings are governed by the rules of practice and procedure for administrative hearings before the OSHA Office of ALJs, and will proceed as follows. 4/ The ALJ generally has discretion to change the below deadlines, however, and the hearing and deadlines may be expedited.

3/ OSHA also reworded some provisions slightly for clarification but did not change their meaning.

4/ The Secretary of Labor amended these rules since OSHA issued the IFR. *See* 80 Fed. Reg. 28785 (May 19, 2015); *see also* 80 Fed. Reg. 37539 (July 1, 2015) (making minor corrections).

- Parties may make pre-hearing motions in writing. Each party has **14 days** after a motion is served to answer it.
- Both parties must file a prehearing statement, and the judge may require the parties to issue a joint prehearing statement.
- The ALJ may order a prehearing conference *sua sponte.*
- Parties may obtain discovery, though ALJs have broad discretion to limit discovery to expedite the hearing.
- At least **30 days** before the hearing, a party may move for a summary decision, and the other party may respond within **14 days.**
- After the hearing, the judge may allow parties to file a post-hearing brief with proposed findings of fact, conclusions of law, and the specific relief sought.

- **Administrative Review Board.** A party seeking review of an ALJ decision may file a written petition for review with the **Administrative Review Board** ("ARB") within **14 days** of the ALJ's decision. ARB has discretion to hear the case, or simply allow the ALJ's decision to become final by not accepting the petition for review within **30 days**.

- **Judicial Review.** *De novo* judicial review in a federal district court is available if there is no final decision by OSHA within (1) **210 days** of the filing of the complaint; or (2) **90 days** after receiving written findings after OSHA's investigation. Review in a federal court of appeals is available after an order by the ARB or after the decision otherwise becomes final.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions or require assistance handling an employee whistleblower matter, please do not hesitate to contact us.