

## CODIFICATION

Another section 1011 of act June 25, 1938, ch. 675, was enacted by Pub. L. 111-148, title III, §3509(g), Mar. 23, 2010, 124 Stat. 536, and is classified to section 399b of this title.

## CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

**§ 399d. Employee protections****(a) In general**

No entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this chapter or any order, rule, regulation, standard, or ban under this chapter, or any order, rule, regulation, standard, or ban under this chapter;<sup>1</sup>

(2) testified or is about to testify in a proceeding concerning such violation;

(3) assisted or participated or is about to assist or participate in such a proceeding; or

(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this chapter, or any order, rule, regulation, standard, or ban under this chapter.

**(b) Process****(1) In general**

A person who believes that he or she has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, not later than 180 days after the date on which such violation occurs, file (or have any person file on his or her behalf) a complaint with the Secretary of Labor (referred to in this section as the "Secretary") alleging such discharge or discrimination and identifying the person responsible for such act. Upon receipt of such a complaint, the Secretary shall notify, in writing, the person named in the complaint of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to such person under paragraph (2).

<sup>1</sup> So in original.

**(2) Investigation****(A) In general**

Not later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the complainant and the person named in the complaint an opportunity to submit to the Secretary a written response to the complaint and an opportunity to meet with a representative of the Secretary to present statements from witnesses, the Secretary shall initiate an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a violation of subsection (a) of the Secretary's findings.

**(B) Reasonable cause found; preliminary order**

If the Secretary concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary shall accompany the Secretary's findings with a preliminary order providing the relief prescribed by paragraph (3)(B). Not later than 30 days after the date of notification of findings under this paragraph, the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order, or both, and request a hearing on the record. The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order. Any such hearing shall be conducted expeditiously. If a hearing is not requested in such 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

**(C) Dismissal of complaint****(i) Standard for complainant**

The Secretary shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

**(ii) Standard for employer**

Notwithstanding a finding by the Secretary that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

**(iii) Violation standard**

The Secretary may determine that a violation of subsection (a) has occurred only if the complainant demonstrates that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

**(iv) Relief standard**

Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

**(3) Final order****(A) In general**

Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary shall issue a final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary, the complainant, and the person alleged to have committed the violation.

**(B) Content of order**

If, in response to a complaint filed under paragraph (1), the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person who committed such violation—

- (i) to take affirmative action to abate the violation;
- (ii) to reinstate the complainant to his or her former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and
- (iii) to provide compensatory damages to the complainant.

**(C) Penalty**

If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

**(D) Bad faith claim**

If the Secretary finds that a complaint under paragraph (1) is frivolous or has been brought in bad faith, the Secretary may award to the prevailing employer a reasonable attorneys' fee, not exceeding \$1,000, to be paid by the complainant.

**(4) Action in court****(A) In general**

If the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination, the complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried

by the court with a jury. The proceedings shall be governed by the same legal burdens of proof specified in paragraph (2)(C).

**(B) Relief**

The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including—

- (i) reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;
- (ii) the amount of back pay, with interest; and
- (iii) compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney's fees.

**(5) Review****(A) In general**

Unless the complainant brings an action under paragraph (4), any person adversely affected or aggrieved by a final order issued under paragraph (3) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complainant resided on the date of such violation. The petition for review must be filed not later than 60 days after the date of the issuance of the final order of the Secretary. Review shall conform to chapter 7 of title 5. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

**(B) No judicial review**

An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

**(6) Failure to comply with order**

Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

**(7) Civil action to require compliance****(A) In general**

A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

**(B) Award**

The court, in issuing any final order under this paragraph, may award costs of litiga-

tion (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

**(c) Effect of section**

**(1) Other laws**

Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law.

**(2) Rights of employees**

Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

**(d) Enforcement**

Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28.

**(e) Limitation**

Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food who, acting without direction from such entity (or such entity's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this chapter.

(June 25, 1938, ch. 675, §1012, as added Pub. L. 111-353, title IV, §402, Jan. 4, 2011, 124 Stat. 3968.)

CONSTRUCTION

Nothing in this section to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

**§ 399e. Nanotechnology**

**(a) In general**

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such nanomaterials, the potential benefit of new therapies derived from nanotechnology, the effects of such nanomaterials on biological systems, and the interaction of such nanomaterials with biological systems.

**(b) Activities**

In conducting activities related to nanotechnology, the Secretary may—

(1) assess scientific literature and data on general nanomaterials interactions with bio-

logical systems and on specific nanomaterials of concern to the Food and Drug Administration;

(2) in cooperation with other Federal agencies, develop and organize information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

(3) promote Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

(4) promote and participate in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

(5) collect, synthesize, interpret, and disseminate scientific information and data related to the interactions of nanomaterials with biological systems;

(6) build scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

(7) ensure ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

(8) encourage the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

(9) carry out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

(Pub. L. 112-144, title XI, §1126, July 9, 2012, 126 Stat. 1116.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This Act, referred to in subsec. (b)(6), is Pub. L. 112-144, July 9, 2012, 126 Stat. 993, known as the Food and Drug Administration Safety and Innovation Act. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

**§ 399f. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups**

**(a) Communication plan**

The Secretary of Health and Human Services (referred to in this section as the "Secretary"),