

§ 360bbb-7. Notification**(a) Notification to Secretary**

With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

- (1) that the use of such drug in the United States may result in serious injury or death;
- (2) of a significant loss or known theft of such drug intended for use in the United States; or
- (3) that—
 - (A) such drug has been or is being counterfeited; and
 - (B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce in the United States; or
 - (ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

(b) Manner of notification

Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

(c) Savings clause

Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.].

(d) Definition

In this section, the term “regulated person” means—

- (1) a person who is required to register under section 360 or 381(s) of this title;
- (2) a wholesale distributor of a drug product; or
- (3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.

(June 25, 1938, ch. 675, §568, as added Pub. L. 112-144, title VII, §715(b), July 9, 2012, 126 Stat. 1075.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 360bbb-8. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments**(a) In general**

For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) Consultation with stakeholders

Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013

through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

(2) Consultation with external experts**(A) In general**

The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary’s regulatory responsibilities and the necessary expertise can be provided by the external experts.

(B) External experts

For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

(b) Topics for consultation

Topics for consultation pursuant to this section may include—

- (1) rare diseases;
- (2) the severity of rare diseases;
- (3) the unmet medical need associated with rare diseases;
- (4) the willingness and ability of individuals with a rare disease to participate in clinical trials;
- (5) an assessment of the benefits and risks of therapies to treat rare diseases;
- (6) the general design of clinical trials for rare disease populations and subpopulations; and
- (7) the demographics and the clinical description of patient populations.

(c) Classification as special government employees

The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18.

(d) Protection of confidential information and trade secrets**(1) Rule of construction**

Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5 as such provisions would be applied to con-