(A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 360b or 360ccc of this title of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;

(B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 360b or 360ccc of this title with due diligence;

(C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and

(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c) of this section.

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) Grants and contracts for development of designated new animal drugs

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term "qualified safety and effectiveness testing" means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 360b of this title; and

(ii) which is carried out under an investigational exemption under section 360b(j) of this title.

(B) The term "manufacturing expenses" means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 360b or 360ccc of this title.

(c) Exclusivity for designated new animal drugs

(1) Except as provided in subsection (c)(2) of this section, if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.

(2) If an application filed pursuant to section 360b of this title or section 360ccc of this title is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under section 360b of this title or section 360ccc of this title for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.

(3) The Secretary shall terminate any discontinuance of the manufacture of such new animal drug at least one year before discontinuance.

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 360b of this title; and

(ii) which is carried out under an investigational exemption under section 360b(j) of this title.

(c) The Secretary shall terminate any discontinuance of the manufacture of such new animal drug upon such notification; and

(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c) of this section.

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) Grants and contracts for development of designated new animal drugs

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term "qualified safety and effectiveness testing" means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 360b of this title; and

(ii) which is carried out under an investigational exemption under section 360b(j) of this title.

(B) The term "manufacturing expenses" means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 360b or 360ccc of this title.

(c) Exclusivity for designated new animal drugs

(1) Except as provided in subsection (c)(2) of this section, if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.
§ 362. Misbranded cosmetics

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

§ 363. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(1938, ch. 675, § 615, 52 Stat. 1034.)

AMENDMENTS


Effect of Amendment

Repeal effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, set out as an Effective Date of 1960 Amendment note under section 379e of this title.
§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346(b), or 352(d) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary. The Secretary shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary re-