

米国における調製粉乳の規定（抜粋）

the Federal Food, Drug, and Cosmetic Act

※ 調製粉乳販売前の FDA 登録に関する規定

§ 350a. Infant formulas

(c) Registration of persons distributing new infant formula

(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, and

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c) (1) of this section.

※ 提出書類に関する規定

(d) Submission of information about new infant formula required

(1) A person shall, with respect to any infant formula subject to subsection (c) of this section, make a submission to the Secretary which shall include—

(A) the quantitative formulation of the infant formula,

(B) a description of any reformulation of the formula or change in processing of the infant formula,

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b) (1) and (i) of this section, as demonstrated by the testing required under subsection (b) (3) of this section, and

(D) assurances that the processing of the infant formula complies with subsection (b) (2) of this section.

the Code of Federal Regulations, CFR

※ 調製粉乳の原材料の規定

§ 106.40 Controls to prevent adulteration caused by ingredients, containers, and closures.

(a) The only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, a substance is used in accordance with the Agency's food additive regulations, is generally recognized as safe (GRAS) for such use, or is authorized by a prior sanction.