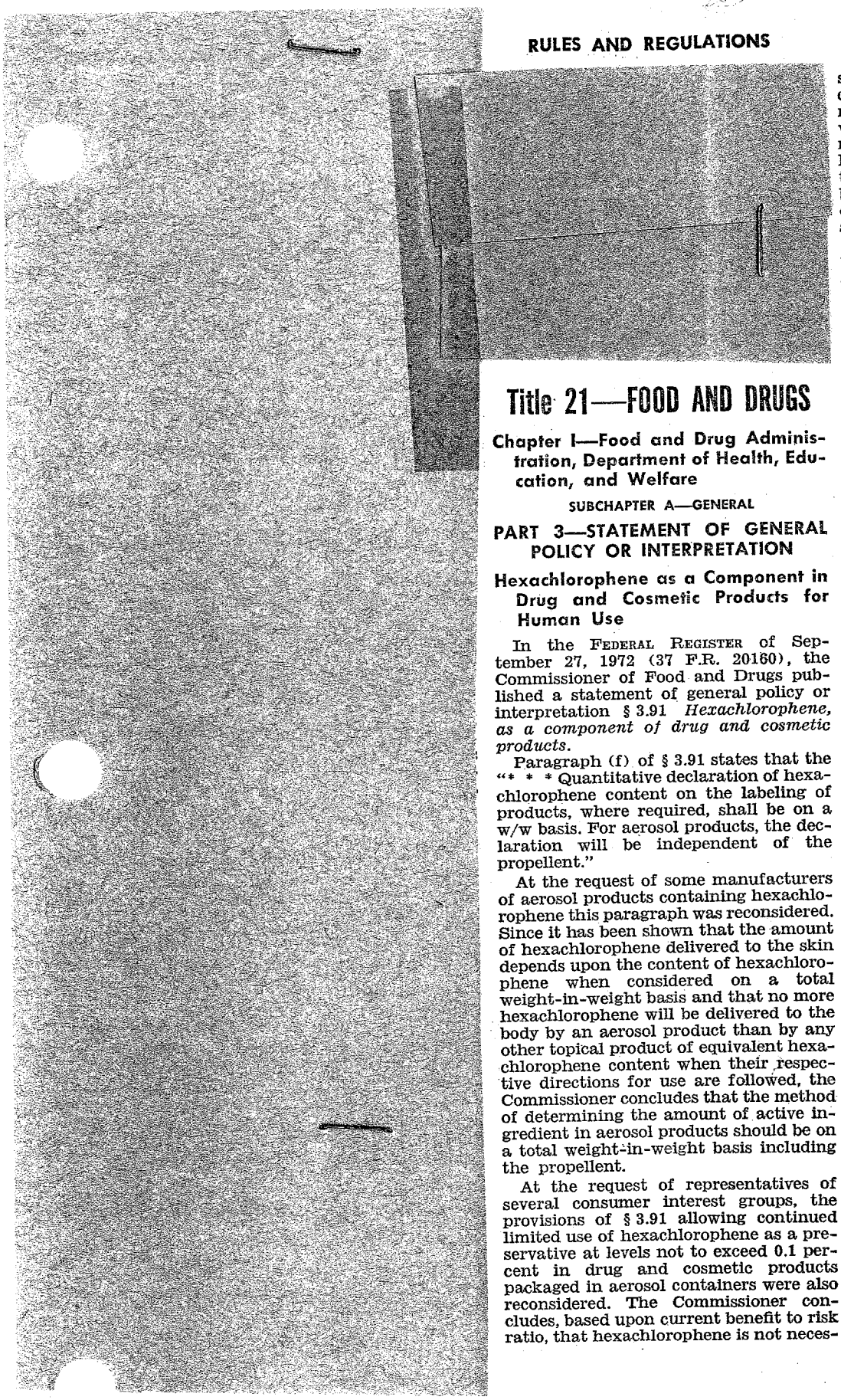

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 3—STATEMENT OF GENERAL POLICY OR INTERPRETATION

Hexachlorophene as a Component in Drug and Cosmetic Products for Human Use

In the FEDERAL REGISTER of September 27, 1972 (37 F.R. 20160), the Commissioner of Food and Drugs published a statement of general policy or interpretation § 3.91 *Hexachlorophene, as a component of drug and cosmetic products.*

Paragraph (f) of § 3.91 states that the "* * * Quantitative declaration of hexachlorophene content on the labeling of products, where required, shall be on a w/w basis. For aerosol products, the declaration will be independent of the propellent."

At the request of some manufacturers of aerosol products containing hexachlorophene this paragraph was reconsidered. Since it has been shown that the amount of hexachlorophene delivered to the skin depends upon the content of hexachlorophene when considered on a total weight-in-weight basis and that no more hexachlorophene will be delivered to the body by an aerosol product than by any other topical product of equivalent hexachlorophene content when their respective directions for use are followed, the Commissioner concludes that the method of determining the amount of active ingredient in aerosol products should be on a total weight-in-weight basis including the propellent.

At the request of representatives of several consumer interest groups, the provisions of § 3.91 allowing continued limited use of hexachlorophene as a preservative at levels not to exceed 0.1 percent in drug and cosmetic products packaged in aerosol containers were also reconsidered. The Commissioner concludes, based upon current benefit to risk ratio, that hexachlorophene is not necessary as a preservative in any drug and/or cosmetic products, which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, e.g., chapsticks, feminine hygiene sprays, rectal ointments, and that § 3.91 should be revised as set forth below to exclude further continued use of hexachlorophene as a preservative in such products.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 502 (a), (f), (j), 503(b), 505, 601(a), 602 (a), (c), 701(a), 52 Stat. 1041, 1050–1055 as amended; 21 U.S.C. 321(n), 352 (a), (f), (j), 353(b), 355, 361(a), 362 (a), (c), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), § 3.91 is amended by revising subparagraph (5) of paragraph (c), the first sentence of paragraphs (d) and (e) and paragraph (f) to read as follows:

§ 3.91 Hexachlorophene, as a component of drug and cosmetic products.

* * * * *

(c) *Prescription drugs.* * * *

(5) Prescription drug products may contain hexachlorophene only as part of an effective preservative system under the conditions and limitations provided for under paragraph (d) of this section.

(d) *Over-the-counter (OTC) drugs.* Over-the-counter drug products, other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, may contain hexachlorophene only as part of an effective preservative system, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. * * *

(e) *Cosmetics.* Hexachlorophene may be used as a preservative in cosmetic products other than those which in normal use may be applied to mucous membranes or which are intended to be used on mucous membranes, at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. * * *

(f) *Content statement.* All reference to hexachlorophene limit in this order is on a weight-in-weight (w/w) basis. Quantitative declaration of hexachlorophene content on the labeling of the products, where required, shall be on a w/w basis.

* * * * *

Effective date. This order shall become effective upon publication in the FEDERAL REGISTER (11–4–72).

(Secs. 201(n), 502(a), (f), (j), 503(b), 505, 601(a), 602(a), (c), 701(a), 52 Stat. 1041, 1050–1055 as amended; 21 U.S.C. 321(n), 352 (a), (f), (j), 353(b), 355, 361(a), 362 (a), (c), 371(a))

Dated: October 31, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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