hand and body creams and lotions; hair
shampoos, hair sets and rinses, hair
straighteners, hair coloring, and other
preparations; bath oils, bubble bath,
and other bath preparations; makeup;
antiperspirants and deodorants; and
eye-area cosmetics.

(b) The toxicity of mercury com-
ounds is extensively documented in
scientific literature. It is well known
that mercury compounds are readily
absorbed through the unbroken skin as
well as through the lungs by inhalation
and by intestinal absorption after in-
gestion. Mercury is absorbed from top-
ical application and is accumulated in
the body, giving rise to numerous ad-
verse effects. Mercury is a potent aller-
gen and sensitizer, and skin irritation
is common after topical application.
Cosmetic preparations containing mer-
cury compounds are often applied with
regularity and frequency for prolonged
periods. Such chronic use of mercury-
containing skin-bleaching preparations
has resulted in the accumulation of
mercury in the body and the occur-
rence of severe reactions. Recently it
has also been determined that micro-
organisms in the environment can con-
vert various forms of mercury into
highly toxic methyl mercury which has
been found in the food supply and is
now considered to be a serious environ-
mental problem.

(c) The effectiveness of mercury-con-
taining preparations as skin-bleaching
agents is questionable. The Food and
Drug Administration has not been pro-
vided with well controlled studies to
document the effectiveness of these
preparations. Although mercurial pres-
ervatives are recognized as highly ef-
effective, less toxic and satisfactory sub-
stitutes are available except in the
case of certain eye-area cosmetics.

(d) Because of the known hazards of
mercury, its questionable efficacy as a
skin-bleaching agent, and the avail-
ability of effective and less toxic non-
mercurial preservatives, there is no
justification for the use of mercury in
skin-bleaching preparations or its use
as a preservative in cosmetics, with the
exception of eye-area cosmetics for
which no other effective and safe non-
mercurial preservative is available.
The continued use of mercurial pre-
servatives in such eye-area cosmetics
is warranted because mercury com-
pounds are exceptionally effective in
preventing Pseudomonas contamination
of cosmetics and Pseudomonas infection
of the eye can cause serious injury, in-
cluding blindness. Therefore:

(1) The Food and Drug Administra-
tion withdraws the opinion expressed
in trade correspondence TC–9 (issued
May 13, 1939) and concludes that any
product containing mercury as a skin-
bleaching agent and offered for sale as
skin-bleaching, beauty, or facial prepa-
rations is misbranded within the mean-
ing of sections 502(a), 502(f)(1) and (2),
and 502(j), and may be a new drug with-
out approval in violation of section 505
of the Federal Food, Drug, and Cos-
metic Act. Any such preparation
shipped within the jurisdiction of the
Act after January 5, 1973 will be the
subject of regulatory action.

(2) The Food and Drug Administra-
tion withdraws the opinion expressed
in trade correspondence TC–412 (issued
Feb. 11, 1944) and will regard as adul-
terated within the meaning of section
601(a) of the Act any cosmetic con-
taining mercury unless the cosmetic
meets the conditions of paragraph
(d)(2) (i) or (ii) of this section.

(i) It is a cosmetic containing no
more than a trace amount of mercury
and such trace amount is unavoidable
under conditions of good manufac-
turing practice and is less than 1 part
per million (0.0001 percent), calculated
as the metal; or

(ii) It is a cosmetic intended for use
only in the area of the eye, it contains
no more than 65 parts per million
(0.0065 percent) of mercury, calculated
as the metal, as a preservative, and
there is no effective and safe nonmer-
curial substitute preservative available
for use in such cosmetic.

§ 700.14 Use of vinyl chloride as an in-
gredient, including propellant of
cosmetic aerosol products.

(a) Vinyl chloride has been used as an
ingredient in cosmetic aerosol products
including hair sprays. Where such aer-
osol products are used in the confines
of a small room, as is often the case,
the level of vinyl chloride to which the

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individual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity, manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the Act is subject to regulatory action.

§ 700.15 Use of certain halogenated salicylanilides as ingredients in cosmetic products.

(a) Halogenated salicylanilides (tribromsalan (TBS,3,4′,5–tribromosalicylanilide), dibromsalan (DBS,4′-dibromosalicylanilide), metabolmsalan (MBS, 3,5–dibromosalicylanilide) and 3,3′,4,5′-tetrachlorosalicylanilide (TCSA)) have been used as antimicrobial agents for a variety of purposes in cosmetic products. These halogenated salicylanilides are potent photosensitizers and cross-sensitizers and can cause disabling skin disorders. In some instances, the photosensitization may persist for prolonged periods as a severe reaction without further exposure to these chemicals. Safer alternative antimicrobial agents are available.

(b) These halogenated salicylanilides are deleterious substances which render any cosmetic that contains them injurious to users. Therefore, any cosmetic product that contains such a halogenated salicylanilide as an ingredient at any level for any purpose is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any cosmetic product containing these halogenated salicylanilides as an ingredient that is initially introduced into interstate commerce after December 1, 1975, that is not in compliance with this section is subject to regulatory action.

§ 700.16 Use of aerosol cosmetic products containing zirconium.

(a) Zirconium-containing complexes have been used as an ingredient in cosmetics and/or cosmetics that are also drugs, as, for example, aerosol antiperspirants. Evidence indicates that certain zirconium compounds have caused human skin granulomas and toxic effects in the lungs and other organs of experimental animals. When used in aerosol form, some zirconium will reach the deep portions of the lungs of users. The lung is an organ, like skin, subject to the development of granulomas. Unlike the skin, the lung will not reveal the presence of granulomatous changes until they have become advanced and, in some cases, permanent. It is the view of the Commissioner that zirconium is a deleterious substance that may render any cosmetic aerosol product that contains it injurious to users.

(b) Any aerosol cosmetic product containing zirconium is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any such cosmetic product introduced in interstate commerce after September 15, 1977 is subject to regulatory action.

§ 700.18 Use of chloroform as an ingredient in cosmetic products.

(a) Chloroform has been used as an ingredient in cosmetic products. Recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice