

First Bill

83^D CONGRESS
1ST SESSION

H. R. 2244

IN THE HOUSE OF REPRESENTATIVES

JANUARY 29, 1953

Mr. DELANEY introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act by providing for the regulation of chemicals in cosmetics.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That section 201 of the Federal Food, Drug, and Cosmetic
4 Act is amended by adding the following paragraph:
5 “(r) The term ‘cosmetic chemical’ means any sub-
6 stance which (1) is intended for use (A) as a cosmetic
7 or component thereof, or (B) to preserve or alter any cos-
8 metic or any characteristic of any cosmetic; and (2) is not
9 generally recognized, among experts qualified by scientific
10 training and experience to evaluate the safety of such sub-
11 stances, as having been adequately tested to show that it is

1 not poisonous or deleterious, or is a poisonous or deleterious
2 substance which is not generally recognized by such experts
3 as having been adequately tested to show that it is safe
4 for use in cosmetics.”

5 SEC. 2. Section 201 (i) (2) of such Act is amended
6 by changing the semicolon to a period and deleting the words
7 “except that such term shall not include soap”.

8 SEC. 3. Section 301 of such Act is amended by chang-
9 ing “404 or 505” in subsection (d) to “404, 505, or 605”;
10 and “404, 505, 506, 507, or 704” in subsection (j) to
11 “404, 505, 506, 507, 605, or 704”.

12 SEC. 4. Section 304 of such Act is amended by chang-
13 ing “404 or 505” in subsection (a) and (d) to “404, 505,
14 or 605”.

15 SEC. 5. Section 601 of such Act is amended by chang-
16 ing subsection (a) to read as follows:

17 “(a) If it bears or contains any poisonous or deleterious
18 substance which may render it injurious to users under the
19 conditions of use prescribed in the labeling thereof, or under
20 such conditions of use as are customary or usual: *Provided,*
21 That this provision shall not apply to articles containing
22 any coal-tar or intermediate thereof which coal-tar or inter-
23 mediate thereof alters the color of the hair, when such articles
24 are applied to the hair under the conditions of use prescribed
25 in the labeling thereof or under such conditions of use as are

1 customary or usual, if the Administrator by regulation finds
2 that such articles may be used by the public without likeli-
3 hood of harm and the label of which bears the following
4 legend conspicuously displayed thereon: Caution—This
5 product contains ingredients which may cause skin irritation
6 on certain individuals and a preliminary test according to
7 accompanying directions should first be made. This product
8 must not be used for dyeing the eyelashes or eyebrows. It
9 must be kept out of the eyes and away from the areas around
10 the eyes. Failure to follow these instructions may result
11 in blindness., and the labeling of which bears adequate
12 directions for such preliminary testing. For the purposes of
13 this paragraph and paragraph (e), the term 'hair dye' shall
14 not include eyelash dyes or eyebrow dyes.”

15 SEC. 6. Section 601 is further amended by adding the
16 following paragraph:

17 “(f) If it bears or contains any cosmetic chemical,
18 unless the use of such cosmetic chemical in such cosmetic
19 has been approved pursuant to section 605.”

20 SEC. 7. Section 602 of such Act is amended by adding
21 the following paragraph:

22 “(e) Unless its labeling bears (1) the common or usual
23 name of the cosmetic chemical, and (2) in case it is fabri-
24 cated from two or more ingredients, the common or usual
25 name of each such ingredient: *Provided*, That to the extent

1 that compliance with the requirements of clause (2) of this
2 paragraph is impracticable, or results in deception or unfair
3 competition, or is not in the best interest of the consumer,
4 exemptions shall be established by regulations promulgated
5 by the Administrator.”

6 SEC. 8. The following section shall be added to chapter
7 VI of such Act:

8 “COSMETIC CHEMICALS

9 “SEC. 605. (a) No person shall introduce or deliver for
10 introduction into interstate commerce any cosmetic chemical,
11 unless the use of such cosmetic chemical has been approved
12 pursuant to subsections (d) or (e).

13 “(b) Any person may file with the Administrator a
14 request for the issuance of an order approving the use of a
15 cosmetic chemical. There shall be submitted to the Admin-
16 istrator as a part of the request (1) reports of investigations
17 which have been made to show the acute and chronic toxic-
18 ity and other potentiality for harm of the cosmetic chemical;
19 (2) a statement of the composition of the cosmetic chemical;
20 (3) a description of methods of analysis for the quantitative
21 determination of the cosmetic chemical in or on cosmetics,
22 including animal tissues if stored therein; (4) such samples
23 of the cosmetic chemical as the Administrator may require;
24 and (5) all directions, recommendations and suggestions
25 proposed for the use of the cosmetic chemical.

1 “(c) After the use of a cosmetic chemical has been ap-
2 proved, the applicant may file a supplemental request setting
3 forth any proposed change in the directions, recommenda-
4 tions and suggestions for the use of the cosmetic chemical or
5 in any other information in the original request.

6 “(d) Unless the Administrator issues a notice of hearing
7 pursuant to subsection (e) prior to the sixtieth day after the
8 date on which a request or supplemental request is filed, the
9 request or supplemental request shall be deemed to have
10 been approved on said sixtieth day for the uses specified;
11 but the Administrator may issue an order approving the re-
12 quest or supplemental request at an earlier date or may post-
13 pone the date on which the request or supplemental request
14 shall be deemed to have been approved until such time (not
15 more than one hundred and eighty days after it has been
16 filed) as the Administrator deems necessary to enable him to
17 conduct the necessary study and investigation.

18 “(e) Unless a request or supplemental request is ap-
19 proved as provided in subsection (d), the Administrator
20 shall give the applicant an opportunity for a hearing for the
21 purpose of determining whether an order shall be issued
22 approving the request or supplemental request. As soon
23 as practicable after completion of the hearing, the Adminis-
24 trator shall notify the applicant of his action in approving
25 or refusing to approve the request or supplemental request.

1 If the Administrator finds that (1) the investigations,
2 reports of which are required to be submitted to him pursu-
3 ant to subsection (b), do not include adequate tests by all
4 methods reasonably applicable to show that the cosmetic
5 chemical is not poisonous or deleterious, or if it is, that it
6 is safe for its intended use; or (2) the results of such tests
7 show that the cosmetic chemical is poisonous or deleterious,
8 and that it is unsafe for such use or do not show that it is
9 safe for such use; or (3) the methods of analysis for the
10 quantitative determination of such cosmetic chemical in
11 cosmetics, including animal tissues if stored therein, are
12 inaccurate or otherwise inadequate; or (4) he has insuffi-
13 cient information to determine whether the cosmetic chemical
14 is poisonous or deleterious, or if it is, whether it is safe for
15 such use, he shall refuse to approve the request or supple-
16 mental request. In determining whether to issue an order
17 approving a request or supplemental request for the use of a
18 cosmetic chemical and the quantity of such cosmetic chemical
19 to be permitted in or on a cosmetic, the Administrator shall
20 take into account the other ways in which the consumer may
21 be affected by the same substance or other substances. The
22 Administrator shall make his order, and any order issued
23 under subsection (f), only after a review of the whole record
24 and in accordance with the reliable, probative, and substantial
25 evidence, and in any such order shall make detailed findings

1 of the facts on which he based his order. Such orders shall be
2 subject to judicial review in accordance with the provisions
3 of section 701 (f).

4 “(f) After notice to the applicant and affording him
5 an opportunity for a hearing, the Administrator may issue
6 an order suspending the approval of a request or supple-
7 mental request with respect to a cosmetic chemical if he
8 finds that (1) experience in the use of the cosmetic chem-
9 ical, tests by new methods, or tests by methods not deemed
10 reasonably applicable when the request or supplemental
11 request was approved, show that the cosmetic chemical is
12 unsafe for any use upon the basis of which the request or
13 supplemental request was approved, or (2) the request or
14 any supplemental request contains any untrue statement of
15 a material fact. The applicant may at any time thereafter
16 request an order terminating the suspension and the Admin-
17 istrator, if reasonable grounds therefor are shown, shall
18 make a prompt investigation and afford the applicant an
19 opportunity for a hearing. The Administrator shall termi-
20 nate the suspension if he finds that adequate measures have
21 been taken to comply with and maintain the provisions of
22 the request or supplemental request.

23 “(g) The Administrator shall promulgate regulation
24 exempting from the operation of this section cosmetic chem-
25 icals intended solely for investigational use by experts quali-

- 1 fed by scientific training and experience to investigate the
- 2 safety of such cosmetic chemicals.”
- 3 SEC. 7. This statute shall take effect six months after
- 4 the date of its enactment.

83D CONGRESS
1ST SESSION

H. R. 2244

A BILL

To amend the Federal Food, Drug, and Cosmetic Act by providing for the regulation of chemicals in cosmetics.

By Mr. DELANEY

JANUARY 29, 1953

Referred to the Committee on Interstate and Foreign Commerce

1 shall notify the applicant of his action in approving or refus-
2 ing to approve the request or supplemental request. If the
3 Administrator finds that (1) the investigations, reports of
4 which are required to be submitted to him pursuant to sub-
5 section (b), do not include adequate tests by all methods
6 reasonably applicable to show that the chemical additive is
7 not poisonous or deleterious, or if it is, that it is safe and
8 required for its intended use; or (2) the results of such tests
9 show that the chemical additive is poisonous or deleterious,
10 and that it is unsafe or not required for such use or do not
11 show that it is safe and required for such use; or (3) the
12 methods of analysis for the quantitative determination of
13 such chemical additive in or on food, including animal and
14 plant tissues if stored therein, or the methods of removal of
15 excessive portions, are inaccurate or otherwise inadequate;
16 or (4) he has insufficient information to determine whether
17 the chemical additive is poisonous or deleterious, or if it is,
18 whether it is safe and required for such use, he shall refuse
19 to approve the request or supplemental request. In deter-
20 mining whether to issue an order approving a request or
21 supplemental request for the use of a chemical additive and
22 the quantity of such chemical additive to be permitted in or
23 on any food, the Administrator shall take into account the
24 extent to which such substance is required in or on such food
25 and the other ways in which the consumer may be affected

and the other ways in which the consumer may be affected
 extent to which such substance is required in or on such food
 on any food. The Administrator shall take into account the
 the quantity of such chemical additive to be permitted in or
 supplemental request for the use of a chemical additive and
 change whether to issue an order approving a request or
 to approve the request or supplemental request. In deter-
 whether it is safe and suitable for use, he shall advise
 the chemical additive is poisonous or deleterious or if it is
 (1) he has established information to determine whether
 such positions are inconsistent or otherwise inadequate
 plant to store it stored therein or the methods of removal of
 range of chemical additive in or on food, including animal and
 method of analysis for the quantitative determination of
 show that it is safe and suitable for such use or (2) the
 method is safe and suitable for such use as the not
 show that the chemical additive is poisonous or deleterious
 for the results of such tests (3) the results of such tests
 are adequate to determine if it is safe and
 reasonable to conclude that the chemical additive is
 safe and suitable for use in or on food.

83d CONGRESS
1ST SESSION

H. R. 2245

A BILL

To amend the Federal Food, Drug, and Cosmetic Act by providing for the regulation of chemical additives in food.

By Mr. DELANEY

JANUARY 29, 1953

Referred to the Committee on Interstate and Foreign
Commerce

2! Bill

84TH CONGRESS
1ST SESSION

H. R. 4475

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 1955

Mr. DELANEY introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to provide for the safety of chemical additives in food.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That section 201 of the Federal Food, Drug, and Cosmetic
4 Act is amended by the addition of the following paragraph:
5 “(s) The term ‘chemical additive’ means any substance
6 (including products resulting from changes in such sub-
7 stance after use) which (1) is intended for use (A) as a
8 food, or (B) to preserve or alter any food or any character-
9 istic of any food; or (C) for any other purpose in producing,
10 processing, packing, transporting, wrapping, or holding food

1 if such use is likely to result in the contamination of food, but
2 shall not include pesticide chemicals used in the production,
3 storage, or transportation of raw agricultural commodities, as
4 defined in section 201 (q) of this Act; and (2) is not gen-
5 erally recognized, among experts qualified by scientific train-
6 ing and experience to evaluate the safety of chemical addi-
7 tives, as having been adequately tested to show that it is
8 not poisonous or deleterious, or is a poisonous or deleterious
9 substance which is not generally recognized among such
10 experts as having been adequately tested to show that it is
11 safe for its intended use.”

12 SEC. 2. Section 301 of the Federal Food, Drug, and
13 Cosmetic Act is amended by changing “404 or 505” in
14 subsection (d) to “404, 409, or 505”; and “404, 505, 506,
15 507, or 704” in subsection (j) to “404, 409, 505, 506,
16 507, or 704”.

17 SEC. 3. Section 304 of such Act is amended by changing
18 “404 or 505” in subsections (a) and (d) to “404, 409, or
19 505”.

20 SEC. 4. Section 402 (a) of such Act is amended by
21 changing the period at the end to a semicolon and adding:
22 “or (7) if it is, or bears or contains, a chemical additive,
23 unless the use of such chemical additive has been approved
24 pursuant to section 409.”

1 SEC. 5. The following section shall be added to chapter
2 IV of such Act:

3 "CHEMICAL ADDITIVES

4 "SEC. 409. (a) No person shall introduce or deliver for
5 introduction into interstate commerce any chemical additive,
6 unless the use of such chemical additive has been approved
7 pursuant to this section.

8 " (b) Any person may file with the Secretary an appli-
9 cation for the issuance of an order approving the use of a
10 chemical additive. There shall be submitted to the Secretary
11 with the application (1) a statement of the intended use of
12 the chemical additive and demonstrating that such employ-
13 ment of the chemical additive will serve a purpose which will
14 be useful to the consuming public; (2) reports of investiga-
15 tions which have been made to determine the acute and
16 chronic toxicity and other potentiality for harm of the chemi-
17 cal additive; (3) a statement of the composition of the
18 chemical additive; (4) a description of methods of analysis
19 for the quantitative determination of the chemical additive,
20 and its reduction products, in or on food; (5) such samples
21 of the chemical additive as the Secretary may require; (6)
22 all directions, recommendations and suggestions proposed for
23 the use of the chemical additive; and (7) if the chemical
24 additive is a poisonous or deleterious substance, reports of

1 investigations which have been made to show the quantities
2 of the chemical additive remaining in or on the food and that
3 it is required for its intended use.

4 “(c) The Secretary shall issue an order approving the
5 application within ninety days after the filing of the applica-
6 tion if the Secretary finds that the reports submitted to him
7 pursuant to subsection (b) demonstrate (1) that the chemi-
8 cal additive is not a poisonous or deleterious substance or if
9 it is that it is safe and required for its intended use, and (2)
10 that the intended use of the chemical additive will serve a
11 purpose which will be useful to the consuming public; other-
12 wise, except as provided in subsection (d), the Secretary
13 shall issue an order within said ninety days refusing to
14 approve the application.

15 “(d) Within said ninety-day period specified in sub-
16 section (c), the Secretary, when he deems such action ad-
17 visable or upon notification from the applicant, shall submit
18 the application and other data before him to an advisory com-
19 mittee to be appointed pursuant to subsection (f). Within
20 sixty days after such referral, or within an additional thirty
21 days if the committee deems such additional time necessary,
22 the committee, after independent study of the data submitted
23 to it by the Secretary, shall certify to him a report and
24 recommendations on the proposal in the application, together
25 with all underlying data and a statement of the reasons for

1 the recommendations. Within thirty days after such cer-
2 tification, the Secretary, after giving due consideration to all
3 the material, including such report and recommendations,
4 then before him, shall issue an order approving the applica-
5 tion if he finds that the chemical additive is not a poisonous
6 or deleterious substance or if it is that it is safe and required
7 for its intended use, and that its intended use will serve a
8 purpose which will be useful to the consuming public; other-
9 wise the Secretary shall issue an order within said thirty
10 days refusing to approve the application. In determining
11 whether a chemical additive is safe under subsection (c) or
12 (d), the Secretary shall take into account the other ways in
13 which the consumer may be affected by the same substance
14 or other substances.

15 “(e) Within thirty days after the issuance of an order
16 under subsection (c) or (d), any person adversely affected
17 may file objections thereto with the Secretary specifying the
18 reasons he deems the order objectionable and requesting a
19 public hearing upon such objections. After furnishing due
20 notice, the Secretary shall thereupon hold a public hearing
21 for the purpose of receiving evidence relevant and material
22 to the issues raised by such objections. Any report, recom-
23 mendations, underlying data and reasons certified to the
24 Secretary by an advisory committee shall be made a part

1 of the record of the hearing. The advisory committee shall
2 designate one of its members to appear and testify at any
3 such hearing with respect to its report and recommendations
4 upon request of the officer conducting the hearing or any
5 person adversely affected: *Provided*, That this shall not pre-
6 clude any other member of the advisory committee from
7 appearing and testifying at such hearing. As soon as prac-
8 ticable after completion of the hearing, the Secretary shall
9 act upon such objections and issue an order. Such order
10 shall be based only on substantial evidence of record at such
11 hearing, including any report, recommendations, underlying
12 data, and reasons certified to the Secretary by an advisory
13 committee, and shall set forth detailed findings of fact upon
14 which the order is based. No such order shall take effect
15 prior to the ninetieth day of its publication, unless the
16 Secretary finds that emergency conditions exist necessitating
17 an earlier effective date, in which event he shall specify in
18 the order his findings as to such conditions.

19 “(f) Whenever an application is referred to an advisory
20 committee, the Secretary shall appoint a committee of com-
21 petent experts to review the application and to make a report
22 and recommendations thereon. Each such advisory com-
23 mittee shall be composed of experts qualified in the subject
24 matter of the application and of adequately diversified pro-
25 fessional background selected by the National Academy of

1 Sciences: *Provided*, That in the event of disability or refusal
2 of the National Academy of Sciences to act, the Secretary
3 shall select such a committee. The size of the committee
4 shall be determined by the Secretary. Members of an ad-
5 visory committee shall receive as compensation for their
6 services a reasonable per diem, which the Secretary shall
7 by rules and regulations prescribe, for time actually spent
8 in the work of the committee, and shall in addition be re-
9 imbursed for their necessary traveling and subsistence ex-
10 penses while so serving away from their places of residence.

11 The members shall not be subject to any other provisions of
12 law regarding the appointment and compensation of em-
13 ployees of the United States. The Secretary shall furnish
14 the committee with adequate clerical and other assistance.

15 “(g) Any person adversely affected, and representa-
16 tives of the Department of Health, Education, and Welfare,
17 shall have the right to consult with any advisory committee
18 provided for in subsection (f) in connection with the appli-
19 cation.

20 “(h) Orders issued under this section, and orders
21 amending or repealing such orders, may be appealed by
22 any person adversely affected in accordance with the pro-
23 visions of section 505 (h): *Provided*, That the findings of
24 the Secretary shall be sustained if supported by substantial
25 evidence when considered on the record as a whole.

1 “(i) The Secretary shall promulgate regulations estab-
2 lishing the procedure by which orders issued under this
3 section may be amended or repealed, and such procedure
4 shall conform to the procedure provided in this section for
5 the promulgation of regulations, including the appointment
6 of advisory committees and the procedure for referring appli-
7 cations to such committees.

8 “(j) The Secretary shall promulgate regulations ex-
9 empting from the operation of this section chemical additives
10 intended solely for investigational use by experts qualified
11 by scientific training and experience to investigate the safety
12 of such chemical additives.”

13 SEC. 6. The Secretary of Health, Education, and Wel-
14 fare, by regulation, shall require the payment of such fees
15 for the performance of the Secretary's functions under this
16 statute as will in the aggregate, in the judgment of the
17 Secretary, be sufficient over a reasonable term to provide,
18 equip, and maintain an adequate service for such function.

19 SEC. 7. This statute shall take effect six months after
20 the date of its enactment.

84TH CONGRESS
1ST SESSION

H. R. 4475

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to provide for the safety of chemical additives in food.

By Mr. DELANEY

FEBRUARY 28, 1955

Referred to the Committee on Interstate and Foreign
Commerce

84TH CONGRESS
1ST SESSION

H. R. 4476

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 28, 1955

Mr. DELANEY introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to provide for the safety of chemicals in cosmetics.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 That section 201 of the Federal Food, Drug, and Cosmetic
4 Act is amended by adding the following paragraph at the
5 end of said section:

6 “The term ‘cosmetic chemical’ means any substance
7 which (1) is intended for use (A) as a cosmetic or com-
8 ponent thereof, or (B) to preserve or alter any cosmetic or
9 any characteristic of any cosmetic; and (2) is not generally

1 recognized, among experts qualified by scientific training
2 and experience to evaluate the safety of such substances, as
3 having been adequately tested to show that it is not poison-
4 ous or deleterious, or is a poisonous or deleterious substance
5 which is not generally recognized by such experts as having
6 been adequately tested to show that it is safe for use in
7 cosmetics.”

8 SEC. 2. Section 301 of such Act is amended by insert-
9 ing “605” in subsections (d) and (j).

10 SEC. 3. Section 304 of such Act is amended by inserting
11 “605” in subsections “a” and “d”.

12 SEC. 4. Section 601 of such Act is amended by changing
13 subsection (a) to read as follows:

14 “(a) If it bears or contains any poisonous or deleterious
15 substance which may render it injurious to users under the
16 conditions of use prescribed in the labeling thereof, or under
17 such conditions of use as are customary or usual: *Provided,*
18 That this provision shall not apply to articles containing any
19 coal tar or intermediate thereof which coal tar or interme-
20 diate thereof alters the color of the hair, when such articles
21 are applied to the hair under the conditions of use prescribed
22 in the labeling thereof or under such conditions of use as are
23 customary or usual, if the Secretary by regulation finds that
24 such articles may be used by the public without likelihood
25 of harm and the label of which bears the following legend

1 conspicuously displayed thereon: 'Caution—This product con-
2 tains ingredients which may cause skin irritation on certain
3 individuals and a preliminary test according to accompanying
4 directions should first be made. This product must not be
5 used for dyeing the eyelashes or eyebrows. It must be kept
6 out of the eyes and away from the areas around the eyes.
7 Failure to follow these instructions may result in blindness.',
8 and the labeling of which bears adequate directions for such
9 preliminary testing. For the purposes of this paragraph and
10 paragraph (e), the term 'hair dye' shall not include eyelash
11 dyes or eyebrow dyes."

12 SEC. 5. Section 601 is further amended by adding the
13 following paragraph:

14 " (f) If it bears or contains any cosmetic chemical, un-
15 less the use of such cosmetic chemical in such cosmetic has
16 been approved pursuant to section 605."

17 SEC. 6. Section 602 of such Act is amended by adding
18 the following paragraph:

19 " (e) Unless its labeling bears (1) the common or usual
20 name of the cosmetic chemical, and (2) in case it is fabri-
21 cated from two or more ingredients, the common or usual
22 name of each such ingredient: *Provided*, That to the extent
23 that compliance with the requirements of clause (2) of this
24 paragraph is impracticable, or results in deception or unfair
25 competition, or is not in the best interest of the consumer,

1 exemptions shall be established by regulations promulgated
2 by the Secretary.”

3 SEC. 7. The following section shall be added to chapter
4 VI of such Act:

5 “COSMETIC CHEMICALS

6 “SEC. 605. (a) No person shall introduce or deliver
7 for introduction into interstate commerce any cosmetic chem-
8 ical, unless the use of such cosmetic chemical has been ap-
9 proved pursuant to this section.

10 “(b) Any person may file with the Secretary an appli-
11 cation for the issuance of an order approving the use of a
12 cosmetic chemical. There shall be submitted to the Secretary
13 as a part of the application (1) reports of investigations
14 which have been made to show the acute and chronic toxicity
15 and other potentiality for harm of the cosmetic chemical;
16 (2) a statement of the composition of the cosmetic chemical;
17 (3) a description of methods of analysis for the quantitative
18 determination of the cosmetic chemical in or on cosmetics,
19 including animal tissues if stored therein; (4) such samples
20 of the cosmetic chemical as the Secretary may require; and
21 (5) all directions, recommendations and suggestions pro-
22 posed for the use of the cosmetic chemical.

23 “(c) The Secretary shall issue an order approving the
24 application within ninety days after the filing of the appli-
25 cation if the Secretary finds that the reports submitted to

1 him pursuant to subsection (b) demonstrate that the cos-
2 metic chemical is not a poisonous or deleterious substance, or
3 if it is that it is safe for its intended use; otherwise, except
4 as provided in subsection (d), the Secretary shall issue an
5 order within said ninety days refusing to approve the
6 application.

7 “(d) Within said ninety-day period specified in sub-
8 section (c), the Secretary, when he deems such action
9 advisable or upon notification from the applicant, shall
10 submit the application and other data before him to an
11 advisory committee to be appointed pursuant to subsection
12 (f). Within sixty days after such referral, or within an
13 additional thirty days if the committee deems such addi-
14 tional time necessary, the committee, after independent
15 study of the data submitted to it by the Secretary, shall
16 certify to him a report and recommendations on the pro-
17 posal in the application, together with all underlying data
18 and a statement of the reasons for the recommendations.
19 Within thirty days after such certification, the Secretary,
20 after giving due consideration to all the material, including
21 such report and recommendations, then before him, shall
22 issue an order approving the application if he finds that
23 the cosmetic chemical is not a poisonous or deleterious sub-
24 stance or if it is that it is safe for its intended use; other-

1 wise the Secretary shall issue an order within said thirty
2 days refusing to approve the application. In determining
3 whether a cosmetic chemical is safe under subsections (c)
4 or (d), the Secretary shall take into account the other ways
5 in which the consumer may be affected by the same sub-
6 stance or other substances.

7 “(e) Within thirty days after the issuance of an order
8 under subsections (c) or (d), any person adversely affected
9 may file objections thereto with the Secretary specifying the
10 reasons he deems the order objectionable and requesting
11 a public hearing upon such objections. After furnishing due
12 notice, the Secretary shall thereupon hold a public hearing
13 for the purpose of receiving evidence relevant and material
14 to the issues raised by such objections. Any report, recom-
15 mendations, underlying data and reasons certified to the
16 Secretary by an advisory committee shall be made a part of
17 the record of the hearing. The advisory committee shall
18 designate one of its members to appear and testify at any
19 such hearing with respect to its report and recommenda-
20 tions upon request of the officer conducting the hearing or
21 any person adversely affected: *Provided*, That this shall
22 not preclude any other member of the advisory committee
23 from appearing and testifying at such hearing. As soon as
24 practicable after completion of the hearing, the Secretary
25 shall act upon such objections and issue an order. Such

1 order shall be based only on substantial evidence of record
2 at such hearing, including any report, recommendations,
3 underlying data, and reasons certified to the Secretary by an
4 advisory committee, and shall set forth detailed findings of
5 fact upon which the order is based. No such order shall
6 take effect prior to the ninetieth day of its publication,
7 unless the Secretary finds that emergency conditions exist
8 necessitating an earlier effective date, in which event he
9 shall specify in the order his findings as to such conditions.

10 “(f) Whenever an application is referred to an advisory
11 committee, the Secretary shall appoint a committee of com-
12 petent experts to review the application and to make a
13 report and recommendations thereon. Each such advisory
14 committee shall be composed of experts qualified in the
15 subject matter of the application and of adequately diversified
16 professional background selected by the National Academy
17 of Sciences: *Provided*, That in the event of disability or
18 refusal of the National Academy of Sciences to act, the
19 Secretary shall select such a committee. The size of the
20 committee shall be determined by the Secretary. Members
21 of an advisory committee shall receive as compensation for
22 their services a reasonable per diem, which the Secretary
23 shall by rules and regulations prescribe, for time actually
24 spent in the work of the committee, and shall in addition
25 be reimbursed for their necessary traveling and subsistence

1 expenses while so serving away from their places of residence.
2 The members shall not be subject to any other provisions
3 of law regarding the appointment and compensation of
4 employees of the United States. The Secretary shall furnish
5 the committee with adequate clerical and other assistance.

6 “(g) Any person adversely affected, and representatives
7 of the Department of Health, Education, and Welfare, shall
8 have the right to consult with any advisory committee pro-
9 vided for in subsection (f) in connection with the application.

10 “(h) Orders issued under this section, and orders
11 amending or repealing such orders, may be appealed by any
12 person adversely affected in accordance with the provisions
13 of section 505 (h) : *Provided*, That the findings of the
14 Secretary shall be sustained if supported by substantial evi-
15 dence when considered on the record as a whole.

16 “(i) The Secretary shall promulgate regulations estab-
17 lishing the procedure by which orders issued under this
18 section may be amended or repealed, and such procedure
19 shall conform to the procedure provided in this section for
20 the promulgation of regulations, including the appointment
21 of advisory committees and the procedure for referring
22 applications to such committees.

23 “(j) The Secretary shall promulgate regulations ex-
24 empting from the operation of this section cosmetic chemicals
25 intended solely for investigational use by experts qualified

1 by scientific training and experience to investigate the safety
2 of such cosmetic chemicals.”

3 SEC. 8. The Secretary of Health, Education, and Wel-
4 fare, by regulation, shall require the payment of such fees
5 for the performance of the Secretary’s functions under this
6 statute as will in the aggregate, in the judgment of the
7 Secretary, be sufficient over a reasonable term to provide,
8 equip, and maintain an adequate service for such function.

9 SEC. 9. This statute shall take effect six months after
10 the date of its enactment.

1 by attending training and experience to investigate the safety
2 of such research chemicals.
3
4 1977 has been established under the Secretary of Health, Education and Welfare
5 and the Department shall have the jurisdiction of such fees
6 and the Secretary shall have the authority to suspend under this
7 act in the event of a violation of the judgment of the
8 Secretary and to suspend or terminate the contract to provide
9 such services and to suspend or terminate the contract after
10 the expiration of the contract.

84TH CONGRESS
1ST SESSION

H. R. 4476

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to provide for the safety of chemicals in cosmetics.

By Mr. DELANEY

FEBRUARY 28, 1955

Referred to the Committee on Interstate and Foreign
Commerce

Food
Final, additive Bill

85TH CONGRESS
1ST SESSION

H. R. 7798

IN THE HOUSE OF REPRESENTATIVES

MAY 28, 1957

Mr. DELANEY introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to provide for the safety of chemical additives in food.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That section 201 of the Federal Food, Drug, and Cosmetic
4 Act is amended by the addition of the following paragraph:
5 “(s) The term ‘chemical additive’ means any substance
6 (including products resulting from changes in such sub-
7 stance after use) which (1) is intended for use (A) as a
8 food, or (B) to preserve or alter any food or any character-
9 istic of any food, including any radioactive material intended
10 for any such use; or (C) for any other purpose in producing,

1 processing, packing, transporting, wrapping, or holding food
2 if such use is likely to result in the contamination of food,
3 including any radioactive material intended for any such use,
4 but shall not include pesticide chemicals used in the produc-
5 tion, storage, or transportation of raw agricultural commodi-
6 ties, as defined in section 201 (q) of this Act; and (2)
7 is not generally recognized, among experts qualified by scien-
8 tific training and experience to evaluate the safety of chemical
9 additives, as having been adequately tested to show that it is
10 not poisonous or deleterious, or is a poisonous or deleterious
11 substance which is not generally recognized among such
12 experts as having been adequately tested to show that it is
13 safe for its intended use.”

14 SEC. 2. Section 301 of the Federal Food, Drug, and
15 Cosmetic Act is amended by changing “404 or 505” in
16 subsection (d) to “404, 409, or 505”; and “404, 505, 506,
17 507, or 704” in subsection (j) to “404, 409, 505, 506,
18 507, or 704”.

19 SEC. 3. Section 304 of such Act is amended by changing
20 “404 or 505” in subsections (a) and (d) to “404, 409, or
21 505”.

22 SEC. 4. Section 402 (a) of such Act is amended by
23 changing the period at the end to a semicolon and adding:
24 “or (7) if it is, or bears or contains, a chemical additive,

1 unless the use of such chemical additive has been approved
2 pursuant to section 409.”

3 SEC. 5. The following section shall be added to chapter
4 IV of such Act:

5 “CHEMICAL ADDITIVES

6 “SEC. 409. (a) No person shall introduce or deliver for
7 introduction into interstate commerce any chemical additive,
8 unless the use of such chemical additive has been approved
9 pursuant to this section.

10 “(b) Any person may file with the Secretary an appli-
11 cation for the issuance of an order approving the use of a
12 chemical additive. There shall be submitted to the Secretary
13 with the application (1) a statement of the intended use of
14 the chemical additive and demonstrating that such employ-
15 ment of the chemical additive will serve a purpose which will
16 be useful to the consuming public; (2) reports of investiga-
17 tions which have been made to determine the acute and
18 chronic toxicity, carcinogenicity, and other potentiality for
19 harm of the chemical additive; (3) a statement of the com-
20 position of the chemical additive; (4) a description of
21 methods of analysis for the quantitative determination of the
22 chemical additive, and its reduction products, in or on food;
23 (5) such samples of the chemical additive as the Secretary
24 may require; (6) all directions, recommendations, and sug-

1 gestions proposed for the use of the chemical additive; and
2 (7) if the chemical additive is a poisonous or deleterious
3 substance, reports of investigations which have been made
4 to show the quantities of the chemical additive remaining in
5 or on the food and that it is required for its intended use.

6 “(c) The Secretary shall issue an order approving the
7 application within ninety days after the filing of the applica-
8 tion if the Secretary finds that the reports submitted to him
9 pursuant to subsection (b) demonstrate (1) that the chemi-
10 cal additive is not a poisonous or deleterious substance or if
11 it is that it is safe and required for its intended use, and (2)
12 that the intended use of the chemical additive will serve a
13 purpose which will be useful to the consuming public; other-
14 wise, except as provided in subsection (d), the Secretary
15 shall issue an order within said ninety days refusing to
16 approve the application.

17 “(d) Within said ninety-day period specified in sub-
18 section (c), the Secretary, when he deems such action ad-
19 visable or upon notification from the applicant, shall submit
20 the application and other data before him to an advisory com-
21 mittee to be appointed pursuant to subsection (f). Within
22 sixty days after such referral, or within an additional thirty
23 days if the committee deems such additional time necessary,
24 the committee, after independent study of the data submitted
25 to it by the Secretary, shall certify to him a report and

1 recommendations on the proposal in the application, together
2 with all underlying data and a statement of the reasons for
3 the recommendations. Within thirty days after such cer-
4 tification, the Secretary, after giving due consideration to all
5 the material, including such report and recommendations,
6 then before him, shall issue an order approving the applica-
7 tion if he finds that the chemical additive is not a poisonous
8 or deleterious substance or if it is that it is safe and required
9 for its intended use, and that its intended use will serve a
10 purpose which will be useful to the consuming public; other-
11 wise the Secretary shall issue an order within said thirty
12 days refusing to approve the application. In determining
13 whether a chemical additive is safe under subsection (c) or
14 (d), the Secretary shall take into account the other ways in
15 which the consumer may be affected by the same substance
16 or other substances, including any hazard to the health of
17 the consumer from food which is yielded by, or derived from,
18 any animal or plant into which such chemical additive has
19 been introduced by feeding or otherwise. The Secretary
20 shall not approve for use in food any chemical additive
21 found to induce cancer in man, or, after tests, found to induce
22 cancer in animals.

23 “(e) Within thirty days after the issuance of an order
24 under subsection (c) or (d), any person adversely affected

1 may file objections thereto with the Secretary specifying the
2 reasons he deems the order objectionable and requesting a
3 public hearing upon such objections. After furnishing due
4 notice, the Secretary shall thereupon hold a public hearing
5 for the purpose of receiving evidence relevant and material
6 to the issues raised by such objections. Any report, recom-
7 mendations, underlying data and reasons certified to the
8 Secretary by an advisory committee shall be made a part
9 of the record of the hearing. The advisory committee shall
10 designate one of its members to appear and testify at any
11 such hearing with respect to its report and recommendations
12 upon request of the officer conducting the hearing or any
13 person adversely affected: *Provided*, That this shall not pre-
14 clude any other member of the advisory committee from
15 appearing and testifying at such hearing. As soon as prac-
16 ticable after completion of the hearings, the Secretary shall
17 act upon such objections and issue an order. Such order
18 shall be based only on substantial evidence of record at such
19 hearing, including any report, recommendations, underlying
20 data, and reasons certified to the Secretary by an advisory
21 committee, and shall set forth detailed findings of fact upon
22 which the order is based. No such order shall take effect
23 prior to the ninetieth day of its publication, unless the
24 Secretary finds that emergency conditions exist necessitating

1 an earlier effective date, in which event he shall specify in
2 the order his findings as to such conditions.

3 “(f) Whenever an application is referred to an advisory
4 committee, the Secretary shall appoint a committee of com-
5 petent experts to review the application and to make a report
6 and recommendations thereon. Each such advisory com-
7 mittee shall be composed of experts qualified in the subject
8 matter of the application and of adequately diversified pro-
9 fessional background selected by the National Academy of
10 Sciences: *Provided*, That in the event of disability or refusal
11 of the National Academy of Sciences to act, the Secretary
12 shall select such a committee. The size of the committee
13 shall be determined by the Secretary. Members of an
14 advisory committee shall receive as compensation for their
15 services a reasonable per diem, which the Secretary shall
16 by rules and regulations prescribe, for time actually spent
17 in the work of the committee, and shall in addition be
18 reimbursed for their necessary traveling and subsistence ex-
19 penses while so serving away from their places of residence.
20 The members shall not be subject to any other provisions
21 of law regarding the appointment and compensation of em-
22 ployees of the United States. The Secretary shall furnish
23 the committee with adequate clerical and other assistance.

24 “(g) Any person adversely affected, and representa-

1 tives of the Department of Health, Education, and Welfare,
2 shall have the right to consult with any advisory commit-
3 tee provided for in subsection (f) in connection with the
4 application.

5 “(h) Orders issued under this section, and orders
6 amending or repealing such orders, may be appealed by
7 any person adversely affected in accordance with the pro-
8 visions of section 505 (h) : *Provided*, That the findings of
9 the Secretary shall be sustained if supported by substantial
10 evidence when considered on the record as a whole.

11 “(i) The Secretary shall promulgate regulations es-
12 tablishing the procedure by which orders issued under this
13 section may be amended or repealed, and such procedure
14 shall conform to the procedure provided in this section for
15 the promulgation of regulations, including the appointment
16 of advisory committees and the procedure for referring
17 applications to such committees.

18 “(j) The Secretary shall promulgate regulations ex-
19 emption from the operation of this section chemical additives
20 intended solely for investigational use by experts qualified
21 by scientific training and experience to investigate the safety
22 of such chemical additives.”

23 SEC. 6. The Secretary of Health, Education, and Wel-
24 fare, by regulation, shall require the payment of such fees
25 for the performance of the Secretary's functions under this

1 statute as will in the aggregate, in the judgment of the
2 Secretary, be sufficient over a reasonable term to provide,
3 equip, and maintain an adequate service for such function.

4 SEC. 7. This statute shall take effect six months after
5 the date of its enactment.

85TH CONGRESS
1ST SESSION

H. R. 7798

A BILL

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Federal Food, Drug, and Cosmetic Act so
as to provide for the safety of chemical
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