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S. 722

To amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements submit to the Food and Drug Administration reports on adverse experiences with dietary supplements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2003

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements submit to the Food and Drug Administration reports on adverse experiences with dietary supplements, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Dietary Supplement
5 Safety Act of 2003”.

1 **SEC. 2. ADVERSE EXPERIENCES WITH DIETARY SUPPLE-**
 2 **MENTS.**

3 (a) IN GENERAL.—Chapter IV of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
 5 ed by adding at the end the following:

6 **“SEC. 416. ADVERSE EXPERIENCES WITH DIETARY SUPPLE-**
 7 **MENTS.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) ADVERSE DIETARY SUPPLEMENT EXPERI-
 10 ENCE.—The term ‘adverse dietary supplement experi-
 11 ence’ means an adverse event that is associated
 12 with the use of a dietary supplement in a human,
 13 without regard to whether the event is known to be
 14 causally related to the dietary supplement.

15 “(2) SERIOUS ADVERSE DIETARY SUPPLEMENT
 16 EXPERIENCE.—The term ‘serious adverse dietary
 17 supplement experience’ means an adverse dietary
 18 supplement experience that—

19 “(A) results in—

20 “(i) death;

21 “(ii) a life-threatening condition;

22 “(iii) inpatient hospitalization or pro-
 23 longation of hospitalization;

24 “(iv) a persistent or significant dis-
 25 ability or incapacity; or

1 “(v) a congenital anomaly, birth de-
2 fect, or other effect regarding pregnancy,
3 including premature labor or low birth
4 weight; or

5 “(B) requires medical or surgical interven-
6 tion to prevent 1 of the outcomes described in
7 subparagraph (A).

8 “(b) REPORTING AND REVIEW.—

9 “(1) SERIOUS ADVERSE DIETARY SUPPLEMENT
10 EXPERIENCES.—

11 “(A) IN GENERAL.—Each manufacturer of
12 a dietary supplement, and each packer or dis-
13 tributor of a dietary supplement the name of
14 which appears on the labeling of the dietary
15 supplement—

16 “(i) shall develop written procedures
17 for—

18 “(I) surveillance, receipt, and
19 evaluation of information on adverse
20 dietary supplement experiences associ-
21 ated with use of the dietary supple-
22 ment; and

23 “(II) submission to the Secretary
24 of reports under this subsection;

1 “(ii) as soon as practicable after, but
 2 in no event later than 15 calendar days
 3 after, initial receipt of information with re-
 4 spect to a serious adverse dietary supple-
 5 ment experience, shall submit to the Sec-
 6 retary—

7 “(I) the information; and

8 “(II) a copy of the current label-
 9 ing for the dietary supplement;

10 “(iii)(I) shall promptly investigate the
 11 adverse dietary supplement experience; and

12 “(II)(aa) if additional information is
 13 obtained, shall submit to the Secretary a
 14 report describing the information—

15 “(AA) not later than 15 days
 16 after obtaining the information; or

17 “(BB) at the request of the Sec-
 18 retary; or

19 “(bb) if no additional information is
 20 obtained, shall maintain records of the
 21 steps taken to seek additional information.

22 “(B) ELIMINATION OF DUPLICATIVE RE-
 23 PORTING.—

24 “(i) IN GENERAL.—To avoid duplica-
 25 tive reporting under this subsection, the

1 Secretary may establish a procedure under
2 which—

3 “(I) a packer or distributor of a
4 dietary supplement may submit a re-
5 port to the manufacturer of the die-
6 tary supplement; and

7 “(II) the manufacturer shall
8 transmit the report to the Secretary.

9 “(ii) REQUIREMENT.—A procedure
10 under clause (i) shall ensure that the Sec-
11 retary receives reports within the applica-
12 ble period of time specified in subpara-
13 graph (A).

14 “(C) CLINICAL EVALUATIONS BY THE SEC-
15 RETARY.—

16 “(i) IN GENERAL.—The Secretary
17 shall conduct a clinical evaluation of each
18 serious adverse dietary supplement experi-
19 ence with a patient that is reported to the
20 Secretary under subparagraph (A).

21 “(ii) UNWILLING PATIENT.—The Sec-
22 retary is not required to conduct a clinical
23 evaluation under clause (i) to the extent
24 that any unwillingness of the patient (or
25 the next of kin for the patient, as the case

1 may be) to cooperate with the evaluation
2 makes it impracticable to conduct the eval-
3 uation.

4 “(2) PERIODIC ADVERSE DIETARY SUPPLEMENT
5 EXPERIENCE REPORTING.—A manufacturer of a die-
6 tary supplement shall annually (or at such shorter
7 intervals as the Secretary may require), in accord-
8 ance with such requirements as the Secretary may
9 establish, submit to the Secretary a report that dis-
10 closes all information received with respect to ad-
11 verse dietary supplement experiences not previously
12 reported under paragraph (1).

13 “(3) REVIEW REGARDING ADVERSE DIETARY
14 SUPPLEMENT EXPERIENCES.—

15 “(A) IN GENERAL.—Promptly after a
16 manufacturer of a dietary supplement receives
17 from a consumer, or obtains by any other
18 means, any information on an adverse dietary
19 supplement experience, the manufacturer shall
20 review the information.

21 “(B) APPLICABILITY.—Subparagraph
22 (A)—

23 “(i) applies to information without re-
24 gard to the source of the information, for-
25 eign or domestic; and

1 “(ii) includes information derived
2 from sources such as—

3 “(I) commercial marketing expe-
4 rience;

5 “(II) postmarketing investiga-
6 tions;

7 “(III) postmarketing surveillance;

8 “(IV) studies;

9 “(V) reports in the scientific lit-
10 erature; and

11 “(VI) unpublished scientific pa-
12 pers.

13 “(4) ADDITIONAL REPORTING REQUIRE-
14 MENTS.—In addition to the requirements of para-
15 graphs (1) and (2), the Secretary may establish such
16 requirements regarding the reporting of information
17 on adverse dietary supplement experiences as the
18 Secretary determines to be appropriate to protect
19 the public health.

20 “(5) WAIVERS.—The Secretary may grant a
21 waiver from the requirement of paragraph (1), (2),
22 or (3) with respect to a dietary supplement if the
23 Secretary determines that compliance with the re-
24 quirement is not necessary to protect the public
25 health.

1 “(6) SYSTEM FOR COORDINATION OF REPORTS
2 RECEIVED BY THE SECRETARY.—With respect to re-
3 ports of adverse dietary supplement experiences sub-
4 mitted to the Secretary (whether required under this
5 subsection or otherwise), the Secretary shall estab-
6 lish a system to—

7 “(A) receive the reports;

8 “(B) refer the reports to the appropriate
9 officials within the Food and Drug Administra-
10 tion;

11 “(C) store and retrieve the reports;

12 “(D) store and retrieve records of activities
13 carried out in response to the reports; and

14 “(E) carry out such other administrative
15 functions regarding the reports as the Secretary
16 determines to be appropriate.

17 “(7) DATA COLLECTION BY SECRETARY.—

18 “(A) IN GENERAL.—The Secretary shall
19 carry out a program to collect data on serious
20 adverse dietary supplement experiences, in addi-
21 tion to receiving reports required in this sub-
22 section.

23 “(B) COOPERATION.—In carrying out the
24 program, the Secretary shall seek the coopera-
25 tion of appropriate public and private entities,

1 including entities that respond to medical emer-
2 gencies.

3 “(8) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated to carry out
5 this subsection \$10,000,000 for fiscal year 2003 and
6 each fiscal year thereafter.

7 “(c) POSTMARKET SURVEILLANCE.—

8 “(1) AUTHORITY TO REQUIRE SURVEIL-
9 LANCE.—The Secretary may by order require a
10 manufacturer of a dietary supplement to conduct
11 postmarket surveillance for the dietary supplement if
12 the Secretary determines that there is a reasonable
13 possibility that a use or expected use of the dietary
14 supplement by a significant number of consumers
15 may result in serious adverse experiences.

16 “(2) SURVEILLANCE PLAN.—

17 “(A) IN GENERAL.—Not later than 30
18 days after receiving from the Secretary an
19 order under paragraph (1) to conduct surveil-
20 lance for a dietary supplement, a manufacturer
21 shall submit to the Secretary, for the approval
22 of the Secretary, a plan for the required surveil-
23 lance.

24 “(B) QUALIFICATIONS REGARDING SUR-
25 VEILLANCE; DATA REGARDING ADVERSE DIE-

1 TARY SUPPLEMENT EXPERIENCES.—Not later
2 than 60 days after a plan is submitted to the
3 Secretary under subparagraph (A), the Sec-
4 retary shall determine whether—

5 “(i) the person designated to conduct
6 the surveillance has appropriate qualifica-
7 tions and experience to conduct the surveil-
8 lance; and

9 “(ii) the plan will result in the collec-
10 tion of useful data that will disclose ad-
11 verse dietary supplement experiences or
12 other information necessary to protect the
13 public health.

14 “(3) SURVEILLANCE PERIOD.—In consultation
15 with a manufacturer of a dietary supplement that is
16 required to conduct surveillance under paragraph
17 (1), the Secretary may by order require a prospec-
18 tive surveillance period for the manufacturer of not
19 more than—

20 “(A) 3 years; or

21 “(B) such longer period as may be deter-
22 mined—

23 “(i) by agreement between the Sec-
24 retary and the manufacturer; or

1 “(ii) if the Secretary and the manu-
2 facturer cannot agree, through a dispute
3 resolution process established by the Sec-
4 retary by regulation.

5 “(d) SAFETY REVIEW FOR POSSIBLY DANGEROUS
6 DIETARY SUPPLEMENTS.—

7 “(1) IN GENERAL.—If a clinical evaluation by
8 the Secretary of 1 or more serious adverse events in-
9 dicates that a dietary supplement or a dietary ingre-
10 dient contained in a dietary supplement appears to
11 present a significant or unreasonable risk of illness,
12 the Secretary may require the manufacturers of the
13 dietary supplement, or of a dietary ingredient con-
14 tained in a dietary supplement, to submit to the Sec-
15 retary data demonstrating that the dietary supple-
16 ment containing the dietary ingredient is safe.

17 “(2) APPROVAL OR DISAPPROVAL OF CONTIN-
18 UED MARKETING.—As soon as practicable after re-
19 ceiving data required under paragraph (1), the Sec-
20 retary shall review the data and issue a determina-
21 tion that—

22 “(A)(i) the dietary supplement is safe; and

23 “(ii) the continued marketing of the die-
24 tary supplement is approved; or

1 “(B)(i) the dietary supplement is not safe
2 or has not been shown to be safe under ordi-
3 nary or frequent conditions of use; and

4 “(ii) the continued marketing of the die-
5 tary supplement is disapproved.”.

6 (b) PROHIBITED ACTS.—Section 301 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
8 ed by adding at the end the following:

9 “(hh) ADVERSE DIETARY SUPPLEMENT EXPERI-
10 ENCES.—

11 “(1) FAILURE TO COMPLY.—The failure of a
12 person to submit a report or comply with any other
13 requirement under section 416.

14 “(2) DISAPPROVAL OF CONTINUED MAR-
15 KETING.—The continued marketing of a dietary sup-
16 plement by any person after the Secretary issues a
17 determination under section 416(d)(2)(B) that—

18 “(A) the dietary supplement is not safe or
19 has not been shown to be safe under ordinary
20 conditions of use; and

21 “(B) the continued marketing of the die-
22 tary supplement is disapproved.”.

1 **SEC. 3. STIMULANTS.**

2 (a) DEFINITION OF STIMULANT.—Section 201 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)
4 is amended by adding at the end the following:

5 “(nn) STIMULANT.—The term ‘stimulant’ means a
6 dietary ingredient that has a stimulant effect on the car-
7 diovascular system or the central nervous system of a
8 human by any means, including—

9 “(1) speeding metabolism;

10 “(2) increasing heart rate;

11 “(3) constricting blood vessels; or

12 “(4) causing the body to release adrenaline.”.

13 (b) PREMARKET APPROVAL.—Chapter IV of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 341 et
15 seq.) (as amended by section 2(a)) is amended by adding
16 at the end the following:

17 **“SEC. 417. STIMULANTS.**

18 “(a) IN GENERAL.—No person shall introduce or de-
19 liver for introduction into interstate commerce a dietary
20 supplement containing a stimulant unless an approval of
21 the dietary supplement under this section is in effect.

22 “(b) APPROVAL.—The Secretary shall approve an ap-
23 plication for premarket approval of a dietary supplement
24 containing a stimulant if the manufacturer of the stimu-
25 lant demonstrates that the dietary supplement is safe
26 under ordinary or frequent conditions of use.

1 “(c) COMBINATIONS OF STIMULANTS.—In the case
2 of a dietary supplement that contains a combination of
3 stimulants, the Secretary, in determining the safety of the
4 dietary supplement, shall consider the interaction of the
5 various stimulants contained in the dietary supplement.

6 “(d) ACTION ON APPLICATION.—The Secretary shall
7 approve or disapprove an application for premarket ap-
8 proval of a dietary supplement containing a stimulant not
9 later than 180 days after receiving the application.”.

10 (c) ADULTERATED FOOD.—Section 402 of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 342) is
12 amended by adding at the end the following:

13 “(i) DIETARY SUPPLEMENTS CONTAINING A STIMU-
14 LANT.—If the food is a dietary supplement containing a
15 stimulant for which the Secretary has not granted pre-
16 market approval under section 417.

17 “(j) EFFECT OF SECTION.—Nothing in this section
18 affects any other law (including a regulation) applicable
19 to caffeine used as a food or drug.”.

20 (d) REGULATIONS.—Not later than 1 year after the
21 date of enactment of this Act, the Secretary of Health and
22 Human Services shall issue guidance for implementing the
23 amendments made by this section.

24 (e) EFFECTIVE DATE.—

1 (1) IN GENERAL.—Except as provided in para-
2 graph (2), the amendments made by this section—

3 (A) apply to dietary supplements manufac-
4 tured before, on, or after the date of enactment
5 of this Act; and

6 (B) take effect on the date that is 180
7 days after the date of enactment of this Act.

8 (2) ALREADY-MARKETED DIETARY SUPPLE-
9 MENTS.—The amendments made by this section do
10 not apply to a dietary supplement that has been
11 marketed before the date of enactment of this Act
12 until the date that is 2 years after the date of enact-
13 ment of this Act.

14 **SEC. 4. STEROID PRECURSORS.**

15 (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
16 Section 201(ff)(1) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 321(ff)(1)) is amended by striking
18 “(other than tobacco)” and inserting “(other than tobacco
19 or a product that bears or contains an anabolic steroid
20 (including a substance that is chemically and pharma-
21 cologically related to testosterone but not including an es-
22 trogen, progestin, or corticosteroid))”.

23 (b) CONTROLLED SUBSTANCES ACT.—

1 (1) DEFINITION OF ANABOLIC STEROID.—Sec-
2 tion 102(41)(A) of the Controlled Substances Act
3 (21 U.S.C. 802(41)(A)) is amended—

4 (A) by striking “that promotes muscle
5 growth, and includes—” and inserting “that
6 promotes muscle growth or is advertised or
7 used to promote muscle growth.

8 “(B) The term ‘anabolic steroid’ includes—”;
9 and

10 (B) by striking “(B)(i)” and inserting
11 “(C)(i)”.

12 (2) EXCLUSION FROM SCHEDULE.—Section
13 201(g)(1) of the Controlled Substances Act (21
14 U.S.C. 811(g)(1)) is amended by striking “if such
15 substance” and all that follows and inserting “if the
16 substance—

17 “(A) is approved as being safe and effective for
18 its intended use under section 505 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

20 “(B) is lawfully marketed under an over-the-
21 counter monograph issued by the Food and Drug
22 Administration.”.

1 **SEC. 5. AGENCY EXPERTISE AND AUTHORITY.**

2 Section 402(f)(1) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 342(f)(1)) is amended by strik-
4 ing the matter following subparagraph (D).

○