

109TH CONGRESS
2^D SESSION

H. R. 5280

To amend the Federal Food, Drug, and Cosmetic Act with respect to the distribution of the drug dextromethorphan, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2006

Mr. UPTON (for himself and Mr. LARSEN of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the distribution of the drug dextromethorphan, 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 “Dextromethorphan
5 Distribution Act of 2006”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Dextromethorphan is a safe and effective
9 active ingredient found in cough suppressant prod-
10 ucts sold over-the-counter in a variety of finished

1 dosage forms, including tablets, gel capsules, pow-
2 ders, and liquids.

3 (2) The bulk powdered form of
4 dextromethorphan is readily available for purchase
5 through various commercial channels.

6 (3) Individuals, including teenagers in par-
7 ticular, are attempting to get high by taking much
8 larger than recommended doses of
9 dextromethorphan.

10 (4) The Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 301 et seq.) and the regulations of the
12 Food and Drug Administration govern the sale of
13 products containing dextromethorphan, the distribu-
14 tion of certain noncontrolled drugs of abuse, and the
15 sale, purchase, trade, and distribution of drug prod-
16 ucts in general.

17 (5) One critical step that should be taken to
18 help combat the abuse of dextromethorphan is to
19 strengthen the Federal controls over the distribution
20 of dextromethorphan in bulk.

21 **SEC. 3. FOOD AND DRUG ADMINISTRATION; RESTRICTIONS**
22 **ON DISTRIBUTION OF UNFINISHED ACTIVE**
23 **INGREDIENTS.**

24 (a) IN GENERAL.—Subchapter A of chapter V of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351

1 et seq.) is amended by inserting after section 503A the
2 following:

3 **“SEC. 503B. RESTRICTIONS ON DISTRIBUTION OF UNFIN-**
4 **ISHED ACTIVE INGREDIENTS.**

5 “(a) IN GENERAL.—If the Secretary determines that
6 the distribution of an unfinished active ingredient should
7 be restricted for the protection of the public health, the
8 Secretary may by regulation prohibit the distribution of
9 the ingredient to any person other than a person reg-
10 istered under section 510, subject to subsections (b) and
11 (c).

12 “(b) FURTHER RESTRICTIONS.—Subsection (a) does
13 not restrict the authority of the Secretary under section
14 201.122 of title 21, Code of Federal Regulations.

15 “(c) DEXTROMETHORPHAN.—Not later than 180
16 days after the date of the enactment of the
17 Dextromethorphan Distribution Act of 2006, the Sec-
18 retary shall issue a final rule under subsection (a) estab-
19 lishing restrictions on the distribution of
20 dextromethorphan.

21 “(d) UNFINISHED ACTIVE INGREDIENT.—For pur-
22 poses of this section, the term ‘unfinished’, with respect
23 to an active ingredient, means an active ingredient that—

24 “(1) is one of the ingredients in a drug that is
25 not in finished dosage form; or

1 “(2) is the sole ingredient of a drug that is not
2 in finished dosage form.”.

3 (b) ENFORCEMENT.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
5 ed by adding at the end the following:

6 “(hh) The distribution of an unfinished active ingre-
7 dient in violation of regulations under section 503B.”.

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