

108TH CONGRESS  
2D SESSION

# H. R. 5306

To amend the Federal Food, Drug, and Cosmetic Act with respect to market exclusivity for cancer drugs, and to amend title 35, United States Code, to provide for the extension of the patent term on such drugs equal to the regulatory review period for such drugs.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2004

Mr. CARTER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to market exclusivity for cancer drugs, and to amend title 35, United States Code, to provide for the extension of the patent term on such drugs equal to the regulatory review period for such drugs.

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 “New War on Cancer  
5 Act”.

1 **SEC. 2. NONPATENT MARKET EXCLUSIVITY FOR CANCER**  
2 **DRUGS.**

3 Chapter V of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 351 et seq.) is amended by adding at the  
5 end the following subchapter:

6 **“Subchapter G—Cancer Drugs**

7 **“SEC. 575. RECOMMENDATIONS FOR INVESTIGATIONS OF**  
8 **CANCER DRUGS.**

9 “(a) **REQUEST FOR RECOMMENDATIONS.**—The spon-  
10 sor of a drug intended for use for cancer (referred to in  
11 this subchapter as a ‘cancer drug’) may request the Sec-  
12 retary to provide written recommendations for the nonclin-  
13 ical and clinical investigations which must be conducted  
14 with the drug before—

15 “(1) it may be approved for use for cancer  
16 under section 505; or

17 “(2) if the drug is a biological product, it may  
18 be licensed for use for cancer under section 351 of  
19 the Public Health Service Act.

20 “(b) **RECOMMENDATIONS.**—If the Secretary has rea-  
21 son to believe that a drug for which a request is made  
22 under subsection (a) is a cancer drug, the Secretary shall  
23 provide the person making the request written rec-  
24 ommendations for the nonclinical and clinical investiga-  
25 tions which the Secretary believes, on the basis of informa-

1 tion available to the Secretary at the time of the request,  
2 would be necessary for—

3 “(1) approval of such drug for use for cancer  
4 under section 505; or

5 “(2) licensing of such drug for use for cancer  
6 under section 351 of the Public Health Service Act.

7 “(c) REGULATIONS.—The Secretary shall by regula-  
8 tion promulgate procedures for the implementation of sub-  
9 sections (a) and (b).

10 **“SEC. 576. DESIGNATION OF CANCER DRUGS.**

11 “(a) REQUEST FOR DESIGNATION.—The sponsor of  
12 a drug may request the Secretary to designate the drug  
13 as a cancer drug. A request for designation of a drug shall  
14 be made before the submission of an application under sec-  
15 tion 505(b) for the drug, or the submission of an applica-  
16 tion for licensing of the drug under section 351 of the  
17 Public Health Service Act. Such a request shall contain  
18 the consent of the applicant to notice being given by the  
19 Secretary under subsection (c) respecting the designation  
20 of the drug.

21 “(b) DESIGNATION.—In the case of a drug for which  
22 a request is submitted under subsection (a), the Secretary  
23 shall designate the drug as a cancer drug if the Secretary  
24 finds that the drug is being or will be investigated for use  
25 for cancer.

1       “(c) CONDITIONS.—A designation of a drug under  
2 subsection (b) shall be subject to the condition that—

3           “(1) after an application is approved for the  
4 drug under section 505(b) or a license is issued for  
5 the drug under section 351 of the Public Health  
6 Service Act, the manufacturer of the drug will notify  
7 the Secretary of any discontinuance of the produc-  
8 tion of the drug at least one year before discontinu-  
9 ance; and

10          “(2) before an application is approved for the  
11 drug under section 505(b) or a license is issued for  
12 the drug under section 351 of the Public Health  
13 Service Act, the sponsor of the drug will notify the  
14 Secretary of any decision to discontinue active pur-  
15 suit of approval of an application under section  
16 505(b) or approval of a license under section 351 of  
17 the Public Health Service Act.

18       “(d) PUBLIC AVAILABILITY OF NOTICE.—Notice re-  
19 specting the designation of a drug under subsection (b)  
20 shall be made available to the public.

21       “(e) REGULATIONS.—The Secretary shall by regula-  
22 tion promulgate procedures for the implementation of sub-  
23 sections (a) and (b).

1 **“SEC. 577. MARKET PROTECTION FOR CANCER DRUGS.**

2       “(a) IN GENERAL.—Except as provided in subsection  
3 (b), if the Secretary approves an application filed pursuant  
4 to section 505 for a drug designated under section 576  
5 as a cancer drug, or if the Secretary issues a license under  
6 section 351 of the Public Health Service Act for such a  
7 drug, the Secretary may not approve another application  
8 under section 505 or issue another license under section  
9 351 of the Public Health Service Act for such drug for  
10 a person who is not the holder of such approved applica-  
11 tion or of such license until the expiration of seven years  
12 from the date of the approval of the approved application  
13 or the issuance of the license. Section 505(c)(2) does not  
14 apply to the refusal to approve an application under the  
15 preceding sentence.

16       “(b) EXCEPTION.—If an application filed pursuant to  
17 section 505 is approved for a drug designated under sec-  
18 tion 576 as a cancer drug or if a license is issued under  
19 section 351 of the Public Health Service Act for such a  
20 drug, the Secretary may, during the seven-year period be-  
21 ginning on the date of the application approval or of the  
22 issuance of the license, approve another application under  
23 section 505 or issue a license under section 351 of the  
24 Public Health Service Act for such drug for cancer for  
25 a person who is not the holder of such approved applica-  
26 tion or of such license if—

1           “(1) the Secretary finds, after providing the  
2 holder notice and opportunity for the submission of  
3 views, that in such period the holder of the approved  
4 application or of the license cannot assure the avail-  
5 ability of sufficient quantities of the drug to meet  
6 the needs of persons with the cancer involved; or

7           “(2) such holder provides the Secretary in writ-  
8 ing the consent of such holder for the approval of  
9 other applications or the issuance of other licenses  
10 before the expiration of such seven-year period.

11 **“SEC. 578. OPEN PROTOCOLS FOR INVESTIGATIONS OF**  
12 **CANCER DRUGS.**

13           “‘If a drug is designated under section 576 as a can-  
14 cer drug and if notice of a claimed exemption under sec-  
15 tion 505(i) or regulations issued thereunder is filed for  
16 such drug, the Secretary shall encourage the sponsor of  
17 such drug to design protocols for the drug which include  
18 persons with the cancer involved who need the drug to  
19 treat the cancer and who cannot be satisfactorily treated  
20 by available alternative drugs.’”.

1 **SEC. 3. ABBREVIATED APPLICATIONS FOR NEW DRUGS;**  
2 **NONPATENT MARKET EXCLUSIVITY FOR CAN-**  
3 **CER DRUGS.**

4 Section 505(j)(5)(F)(ii) of the Federal Food, Drug,  
5 and Cosmetic Act (21 U.S.C. 355(j)(5)(F)(ii)) is amend-  
6 ed—

7 (1) by striking “(ii)” and inserting “(ii)(I)”;

8 and

9 (2) by adding at the end the following sub-  
10 clause:

11 “(II) With respect to an application under subsection  
12 (b) for a drug referred to in subclause (I), in any case  
13 in which the drug is for use for cancer, the reference in  
14 such subclause to five years is deemed to be ten years,  
15 the reference to four years is deemed to be eight years,  
16 the reference to forty-eight months is deemed to be ninety-  
17 six months, and the reference to seven and one-half years  
18 is deemed to be twelve and one-half years.”.

19 **SEC. 4. EXTENSION OF PATENT TERM ON CANCER DRUGS.**

20 Section 156(c) of title 35, United States Code, is  
21 amended by adding at the end the following flush sen-  
22 tence:

23 “Paragraphs (2) and (3) shall not apply in the case of  
24 a drug approved for use for cancer.”.

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