Annex to C. SCIT 2505

Country | United States

QUESTIONNAIRE

ON THE GRANT AND PUBLICATION OF "SUPPLEMENTARY PROTECTION CERTIFICATES" FOR MEDICINAL AND PHYTOPHARMACEUTICAL PRODUCTS OR EQUIVALENT INDUSTRIAL PROPERTY RIGHTS *(SPCs)*

Important Remarks

1. The survey published in 1997 concerned only "Supplementary Protection Certificates" for medicinal products or equivalent industrial property titles of protection, but not the "Supplementary Protection Certificates" for phytopharmaceutical products.

2. This questionnaire aims at updating the 1997 survey and at including the industrial property titles of protection for phytopharmaceutical products.

3. In order to facilitate the updating of the said survey and the inclusion of information on phytopharmaceutical products, appropriate entries have been added. For the purposes of the survey, medicinal products and phytopharmaceutical products are both covered by the abbreviation "SPCs."

4. The survey will be made available through the WIPO Web site and will be kept up to date. For this purpose, you are kindly requested to inform the International Bureau of any change in the applicable legislation in your country.

5. Offices not covered by the previous survey are kindly requested to provide information as available.

6. If your Office participated in the previous survey and there are no changes, please indicate "no change."

7. Please, refer to Part 7.2.1 of the WIPO "Handbook on Industrial Property Information and Documentation" when responding to the following questions:

Question 1: **Does your Office grant "supplementary protection certificates" for medicinal products or equivalent industrial property rights (SPCs) that extend the validity of patents covering medicinal, pharmaceutical, agrochemical or cognate products and phytopharmaceutical products?**

(a) In the field of medicinal products

Yes **X**

No □

(b) In the field of phytopharmaceutical products

Yes **X**

No □

Question 2: **Will your Office start granting SPCs in the future?**

(a) In the field of medicinal products

Yes **N/A**

No □

(b) In the field of phytopharmaceutical products

Yes **N/A**

□

No □

Question 3: **Please, specify the legal basis for granting SPCs (national law, regional regulation, etc.).**

(a) In the field of medicinal products

(1) Laws **United States Code (U.S.C.), Title 35 Patents , Sections 155, 155A, and 156 on Extension of Patent Term: 35 U.S.C. § 155 – 156 (2000) and Code of Federal Regulations (C.F.R.) Rules of Practice in Patent cases, Extension of Patent term: 37 C.F. R. § 1.710 – 1.785 (2000).**

(2) Decrees, ordinances

(3) Other

(b) In the field of phytopharmaceutical products

(1) Laws **United States Code (U.S.C.), Title 35 Patents , Sections 155, 155A, and 156 on Extension of Patent Term: 35 U.S.C. § 155 – 156 (2000) and Code of Federal Regulations (C.F.R.) Rules of Practice in Patent cases, Extension of Patent term: 37 C.F. R. § 1.710 – 1.785 (2000).**

(2) Decrees, ordinances

(3) Other

Question 4: Please specify the name of the SPC granted by your Office.

(a) In the field of medicinal products
Certificate Extending Patent Term Under 35 U.S.C. 156.

(b) In the field of phytopharmaceutical products
Certificate Extending Patent Term Under 35 U.S.C. 156.

Question 5: Please specify for which fields of technology or which products an SPC can be obtained (for example, medicinal products, phytopharmaceutical products, herbicides, agro-chemicals, all products subject to regulatory approval for marketing, etc.).

Human drug, antibiotic drug, or human biological product (as those terms are used in the U.S. Federal Food, Drug, and Cosmetic and the Public Health Services Act), new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridaoma technology, or other processes involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient , as a single entity or in combination with another active ingredient, and any medical device, food additive, or color additive subject to regulation under the federal Food, Drug, and Cosmetic Act.

Question 6: Does your Office publish or intend to publish the receipt of an application for an SPC?

(If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding SPCs made in an Official Gazette.)

No, but the Food and Drug Administration publishes a determination related to the filing of an application for patent term extension, including the approval date of the product and the new drug application (or other application) number. See the attached Federal Register Notice for an example.

(a) In the field of medicinal products

Yes □

No **X**

(b) In the field of phytopharmaceutical products

Yes □

No **X**

Question 7: If your reply to question 6 is "Yes," please indicate the minimum elements a publication must contain:

(a) In the field of medicinal products

(i) number alloted to receipt of the application

(ii) date of said receipt

(iii) name and address of the applicant

(iv) number of the basic patent

(v) title of the invention

(vi) number of any authorization to place the product on the market, including the product identified in that authorization

(vii) date of the said authorization

(viii) other elements (please specify)

(b) In the field of phytopharmaceutical products

(i) number alloted to receipt of the application

(ii) date of said receipt

(iii) name and address of the applicant

(iv) number of the basic patent

(v) title of the invention

(vi) number of any authorization to place the product on the market, including the product identified in that authorization

(vii) date of the said authorization

(viii) other elements (please specify)

Question 8: **Does your Office publish or intend to publish the fact that an SPC has been granted? YES**

(If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding the grant of SPCs made in an Official Gazette.)

(a) In the field of medicinal products

A sample *Official Gazette* Notice Follows:

PATENT TERM EXTENDED UNDER 35 U.S.C. 156

A Certificate extending the term of the following patent was issued on ____. U.S. Patent No.:___; Granted:___; Applicant:___; Owner of Record:___; Title:___; Classification:___; Product Trade Name:___; Original Expiration Date:___; Term Extended:___ ; Extended Expiration Date:___.

(b) In the field of phytopharmaceutical products **same as above**.

Question 9: **If your reply to question 8 is "Yes," please indicate the minimum elements a publication must contain:**

(a) In the field of medicinal products

(i) registration number allotted to the granted SPC
No specific registration number is allotted. The publication number of the patent is used.

(ii) date of registration of the granted SPC **Yes**

(ii) name and address of the holder of the SPC
Yes, but Office publishes the name only.

(iv) number of the basic patent **Yes**

(v) title of the invention **Yes**

(vi) number of any authorization to place the product on the market, including the product identified in that authorization **No**

(vii) date of the said authorization **No**

(viii) duration of the SPC **Yes**

(ix) other elements, e.g., patent classification, product name (please specify): **Patent Grant date, applicant, owner of record, patent classification, product trade name**

(b) In the field of phytopharmaceutical products

(i) registration number allotted to the granted SPC
No specific registration number is allotted. The publication number of the patent is used.

(ii) date of registration of the granted SPC **Yes**

(ii) name and address of the holder of the SPC
Yes, but Office publishes the name only.

(iv) number of the basic patent **Yes**

(v) title of the invention **Yes**

(vi) number of any authorization to place the product on the market, including the product identified in that authorization **No**

(vii) date of the said authorization **No**

(viii) duration of the SPC **Yes**

(ix) other elements, e.g., patent classification, product name (please specify):): **Patent Grant date, applicant, owner of record, patent classification, product trade name**

Question 10: In which form does your Office make or intend to make the publications referred to in questions 6 and 8?

(a) In the field of medicinal products
(i) As regards applications for SPCs

(a) as part of an Official Gazette? **No**

(b) by publishing the application?**No**

(c) by laying the application open to public inspection? **Yes.**

(d) through online databases (or the Office's Web site)? **No**

(e) by copy delivery of the application on request? **No**

(ii) As regards granted SPCs

(a) as part of an Official Gazette? **Yes**

(b) by publishing the SPC? **No**

(c) by laying the SPC open to public inspection? **Yes**

(c) through online databases (or the Office's Web site)? **Yes**
Patent number, approved product, extension period, and Official Gazette notice date are available online and full patent text for Patents issued 1 January 1976 to most recent.

(e) by copy delivery of the SPC on request? **Yes**

(b) In the field of phytopharmaceutical products

(i) As regards applications for SPCs

(a) as part of an Official Gazette? **No**

(b) by publishing the application? **No**

(c) by laying the application open to public inspection? **Yes**

(d) through online databases (or the Office's Web site)? **No**

(e) by copy delivery of the application on request? **No**

(ii) As regards granted SPCs

(a) as part of an Official Gazette? **Yes**

(b) by publishing the SPC? **No**

(c) by laying the SPC open to public inspection? **Yes**

(d) through online databases (or the Office's Web site)? **Yes**
Patent number, approved product, extension period, and Official Gazette notice date are available online and full

patent text for Patents issued 1 January 1976 to most recent.

(e) by copy delivery of the SPC on request? **Yes**

Question 11: **If your Office enters or intends to enter data from the documents relating to SPCs in online databases (internal or commercial ones), please indicate the names(s) of the databases(s) and specify the bibliographic data elements:**

(a) In the field of medicinal products

(i) name(s) of database(s)
Patent Term Extension
USPTO Web Patent Database

(ii) bibliographic data elements
Elements as specified in reply to Question 10.

(b) In the field of phytopharmaceutical products

(i) name(s) of database(s)

Patent Term Extension
PTO Web Patent Database

(iii) bibliographic data elements
Elements as specified in reply to Question 10.

Question 12: **If your Office allots or intends to allot specific application and/or registration numbers to SPCs, please give details:**

(a) As regards medicinal products

(i) concerning the numbering system for applications for SPCs
Publication number of the patent is used.

(ii) concerning the numbering system for registrations or grants of SPCs (if different from (a)(i))

(b) As regards phytopharmaceutical products

(i) concerning numbering system for applications for SPCs
Publication number of the patent is used.

(ii) concerning the numbering system for registrations or grants of SPCs (if different from (b)(i))

Contact details:

(a) Name: Ms. Cherie Kazenske

(b) Title: Intellectual Property Program Manager

(c) Office/Organization: Office of Legislative and International Affairs
U.S. Patent and Trademark Office

(d) E-mail: cherie.kazenske@uspto.gov

(e) Facsimile: (703)305-8885

(f) Telephone: (703) 305-9300

[End of Questionnaire]

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Ziagen™ (abacavir). Ziagen™ is indicated for the treatment of HIV–1 infection. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Ziagen™ (U.S. Patent No. 5,034,394) from Glaxo Wellcome, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 1999, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Ziagen™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ziagen™ is 1,632 days. Of this time, 1,455 days occurred during the testing phase of the regulatory review period, while 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* July 1, 1994. The applicant claims June 28, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* June 24, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Ziagen™ (NDA 20–977) was initially submitted on June 24, 1998.

3. *The date the application was approved:* December 17, 1998. FDA has verified the applicant's claim that NDA 20–977 was approved on December 17, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 906 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 25, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 25, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–1871 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0853]

Determination of Regulatory Review Period for Purposes of Patent Extension; GlucaGen®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GlucaGen® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug

products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GlucaGen® (glucagon (rDNA origin)). GlucaGen® is indicated for the treatment of hypoglycemia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GlucaGen® (U.S. Patent No. 4,826,763) from Novo Nordisk A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 27, 1999, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GlucaGen® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GlucaGen® is 2,569 days. Of this time, 2,296 days occurred during the testing phase of the regulatory review period, while 273 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* June 12, 1991. The applicant claims June 13, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 12, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* September 23, 1997. The applicant claims September 18, 1997, as the date the new drug application (NDA) for GlucaGen® (NDA 20–918) was initially submitted. However, FDA records indicate that NDA 20–918 was submitted on September 23, 1997.

3. *The date the application was approved:* June 22, 1998. FDA has verified the applicant's claim that NDA 20–918 was approved on June 22, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,423 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 21, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 25, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–1872 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–0119]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sentinel Model 2000/2010®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Sentinel Model 2000/2010® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Sentinel Model 2000/2010®. Sentinel Model 2000/2010® is indicated for use in patients with documented ventricular fibrillation and/or ventricular tachycardia, or in