Linkages Between Generic Approval and the Patent System in the United States

Karin L. Ferriter
Patent Attorney
Office of Intellectual Property Policy and Enforcement
USPTO
(571) 272-9300
karin.ferriter@uspto.gov

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TRIPs Article 33 - Term of Protection

- Article 33 provides that the term of protection for a patent shall not end before the expiration of a period of twenty years counted from the filing date.
- Leaves open the possibility of patent term extensions in instances when circumstances warrant patent extension.

Patent Term Extension under 35 U.S.C. 156

Patent Term Extension under 35 U.S.C. 156

Conditions for extension:

1) The patent had not expired before an application was filed
2) The patent has never been extended under 35 USC 156(e)(1)
3) The application for extension is submitted within 60 days of FDA approval of the product
4) The product has been subject to a regulatory review before its commercial marketing or use
5) The approval is the first permitted commercial marketing or use of the product (with some exceptions)

Patent Term Extension under 35 U.S.C. 156

- "Product" means:
  - The active ingredient of a new human drug, antibiotic drug, or human biological product
  - The active ingredient of a new animal drug or veterinary biological product
  - Any medical device, food additive or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act

Patent Term Extension under 35 U.S.C. 156

- A patent is considered to claim the product if the patent claims the active ingredient *per se*, or claims a composition or formulation which contains the active ingredient(s) and the claim covers the composition or formulation approved for commercial marketing or use

Patent Term Extension under 35 U.S.C. 156

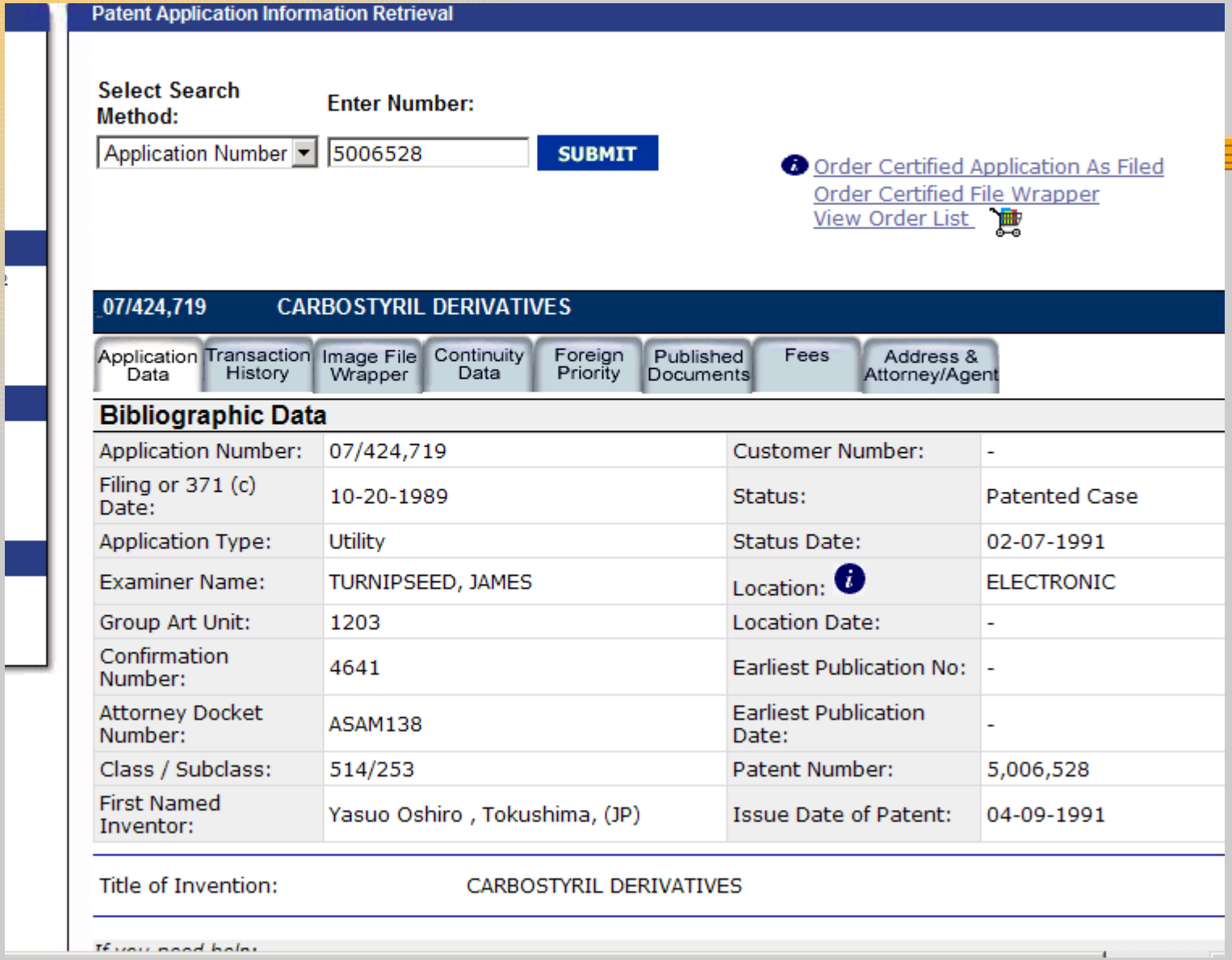
- Where a product contains multiple active ingredients, if any one active ingredient has not been previously approved, it can form the basis of an extension of patent term provided the patent claims that ingredient

Patent Term Extension under 35 U.S.C. 156

- A new animal drug or veterinary biological product may be extended based on a second or subsequent approval of the active ingredient provided:

1) The patent claims the drug or product
2) The drug or product is not covered in another patent that has been extended
3) The patent term was not extended on the basis of the regulatory review period for use in non-food producing animals
4) The second or subsequent approval was the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal

Application for Patent Term Extension on USPTO Internet Website



Patent Application Information Retrieval

Select Search Method: Application Number

Enter Number: 5006528 SUBMIT

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07/424,719 CARBOSTYRIL DERIVATIVES

Application Data | Transaction History | Image File Wrapper | Continuity Data | Foreign Priority | Published Documents | Fees | Address & Attorney/Agent

Bibliographic Data

Application Number:	07/424,719	Customer Number:	-
Filing or 371 (c) Date:	10-20-1989	Status:	Patented Case
Application Type:	Utility	Status Date:	02-07-1991
Examiner Name:	TURNIPSEED, JAMES	Location:	ELECTRONIC
Group Art Unit:	1203	Location Date:	-
Confirmation Number:	4641	Earliest Publication No:	-
Attorney Docket Number:	ASAM138	Earliest Publication Date:	-
Class / Subclass:	514/253	Patent Number:	5,006,528
First Named Inventor:	Yasuo Oshiro , Tokushima, (JP)	Issue Date of Patent:	04-09-1991

Title of Invention: CARBOSTYRIL DERIVATIVES

Application for Patent Term Extension on USPTO Internet Website

This application is officially maintained in electronic form. To View: Click the desired Document Description. To Download Print: Check the desired document(s) and click StartDownload.

Mail Room Date	Document Description	Page Count	Select All	Start Download
10-14-2005	Patent Term Extension Certificate	2	☐	
06-23-2004	FDA Final Eligibility Letter	1	☐	
11-26-2003	Transaction for FDA Determination of Regulatory Review Period	2	☐	
11-03-2003	Transaction for FDA Determination of Regulatory Review Period	2	☐	
08-11-2003	Letter RE: PTE Application to FDA or Dept. of Agriculture	1	☐	
06-16-2003	Letter from FDA or Dept. of Agriculture RE: PTE Application	1	☐	
01-16-2003	Letter RE: PTE Application to FDA or Dept. of Agriculture	1	☐	
01-07-2003	Patent Term Extension Application Under 35 USC 156	75	☐	
03-04-1992	Miscellaneous Incoming Letter	4	☐	
04-09-1991	Foreign Priority Papers Filed	1	☐	
01-24-1991	Miscellaneous Incoming Letter	2	☐	
10-24-1990	Notice of Allowance and Fees Due (PTOL-85)	4	☐	
10-24-1990	Examiner Interview Summary Record	1	☐	

PDF viewer - Microsoft Internet Explorer provided by USPTO

File: 07424719

Page No.: 1 of 75 pages

Patent Term Extension Application

Select 67% Sign

Pages Attachments Comments

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OFFICE OF PETITIONS

PATENT
Atty. Docket No.: 3459.0027

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,006,528

Issued: April 9, 1991

To: Yasuo Oshiro, Seiji Sato, Nobuyuki Kurahashi

Assignee: Otsuka Pharmaceutical Co., Ltd.

For: CARBOSTYRIL DERIVATIVES

ATTN: BOX PATENT EXT.
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Applicant, Otsuka Pharmaceutical Co., Ltd., represents that it is the Assignee of the entire interest in and to United States Patent No. 5,006,528 granted to Yasuo Oshiro, Seiji Sato, and Nobuyuki Kurahashi on the 9th day of April, 1991, for Carbostyril Derivatives by virtue of an assignment in favor of Otsuka Pharmaceutical Co., Ltd. The assignment to Otsuka Pharmaceutical Co., Ltd. was recorded at Reel 5162, Frame 0548 on October 20, 1989. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., including

1 of 1

U.S. Patent Term Extension Certificate

PATENT NO.	:	4,379,785
ISSUED	:	April 12, 1983
INVENTOR(S)	:	Rudi Weyer et al.
PATENT OWNER	:	Hoechst Atiengesellschaft

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,571 days

from December 17, 2000, the original expiration date of the patent, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the Patent and Trademark Office to be affixed this 5th day of September 1997.

Bruce A. Lehman

Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

Image of Certificate Exter

"Patent Linkage"
In the United States

Overview

- A mechanism to promote effective and adequate protection of intellectual property rights: Patent Linkage
- Orange Book patent listings

Objective of TRIPs

- Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. (Introduction to TRIPS Annex C)

- Any system of patent linkage should keep this dual goal in mind: promote both IP rights and trade.

An Efficient Balance with "Patent Linkage"

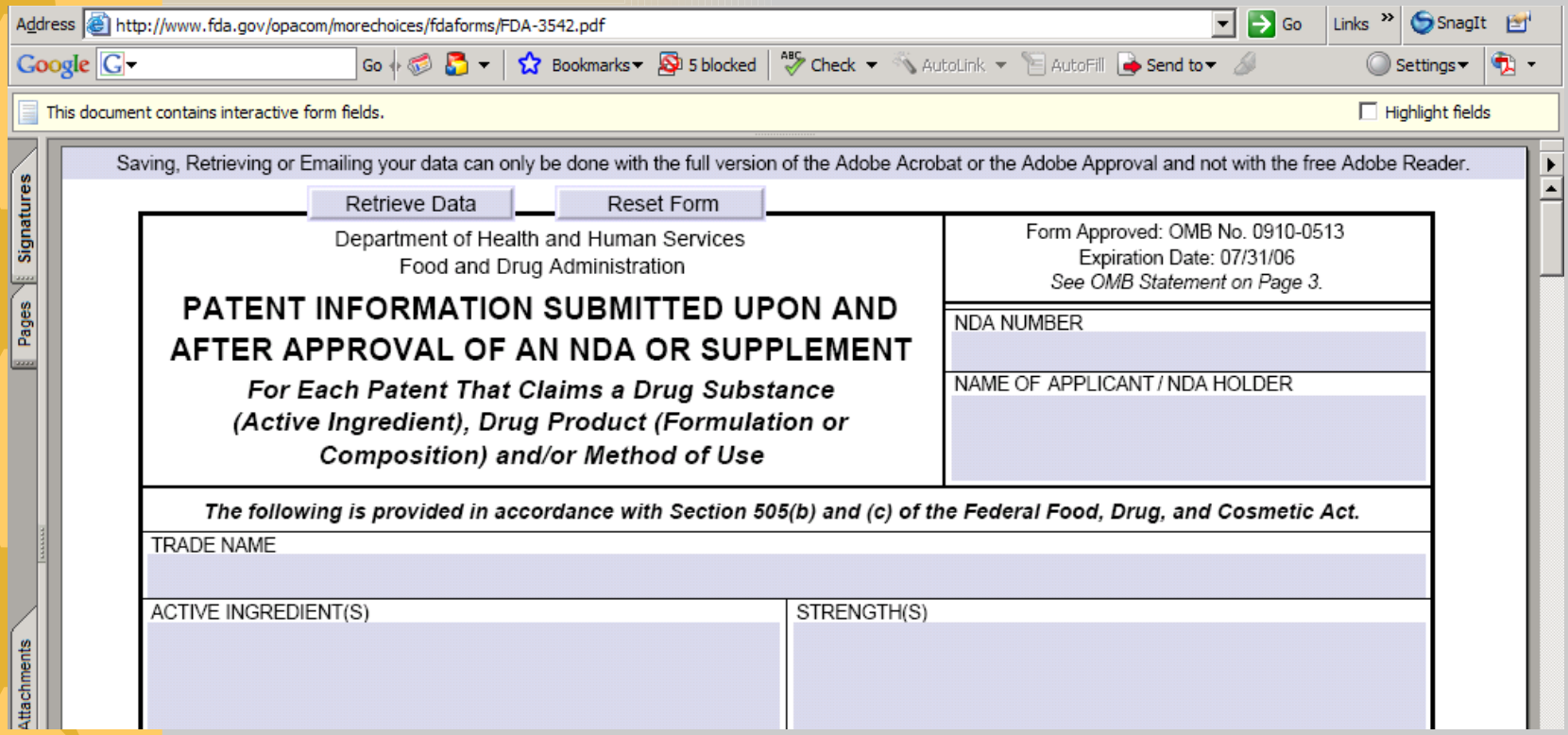
- New Drug Application (NDA) must include patent information and the FDA considers the existence of patents as part of the approval process for certain drug applications
- If a patent exists, marketing approval will not be granted to a generic until the patent has expired or is found to be invalid.
- This is Patent Linkage: Generic Marketing Approval is "Linked" to the Expiration of the Pioneer Drug Patent

Patent Linkage

- Patent Information Can be Obtained Efficiently:
  - US FDA Requires Applicant to list patents that cover the drug as part of NDA filing
  - Applicant Must submit signed declaration
  - FDA relies on innovator drug company's assertion
  - Patent information published in Orange Book

How FDA becomes aware of patents:

- Forms 3542 and 3542a (available at www.fda.gov)



Required to list patents that cover the drug as part of NDA filing

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii) at the address provided in 21 CFR 314.53(d)(4). To expedite review of this patent declaration form, you may submit an additional copy of this declaration form to the Center for Drug Evaluation and Research "Orange Book" staff.

For hand-written or typewriter versions of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the approved NDA or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this NDA or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent

d. Name of Patent Owner	Address *(of Patent Owner)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

e. Name of agent or representative who resides or main-	Address *(of agent or representative named in 1.e.)*

Must submit signed declaration

5. No Relevant Patents

For this NDA or supplement, there are no relevant patents that claim the approved drug substance (active ingredient) or the approved drug product (formulation or composition) or approved method(s) of use with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*

Date Signed

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☐ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

FDA will rely upon the information Submitted

3. Drug Product (Composition/Formulation)		
3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3?	☐ Yes	☐ No
3.2 Does the patent claim only an intermediate?	☐ Yes	☐ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No
FDA will not list the patent in the Orange Book as claiming the drug product if: • **the answer to question 3.1 is "No," or,** • **the answer to question 3.2 is "Yes," or,** • **the answer to question 3.3 is "No."**		
4. Method of Use		
Sponsors must submit the information in section 4 separately for each patent claim claiming an approved method of using the approved drug product. For each method of use claim referenced, provide the following information:		
4.1 Does the patent claim one or more approved methods of using the approved drug product?	☐ Yes	☐ No
4.2 Patent Claim Number *(as listed in the patent)*	Does the patent claim referenced in **4.2** claim an approved method of use of the approved drug product? ☐ Yes ☐ No	
4.2a If the answer to **4.2** is "Yes," identify the use with specific reference to the approved labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*	

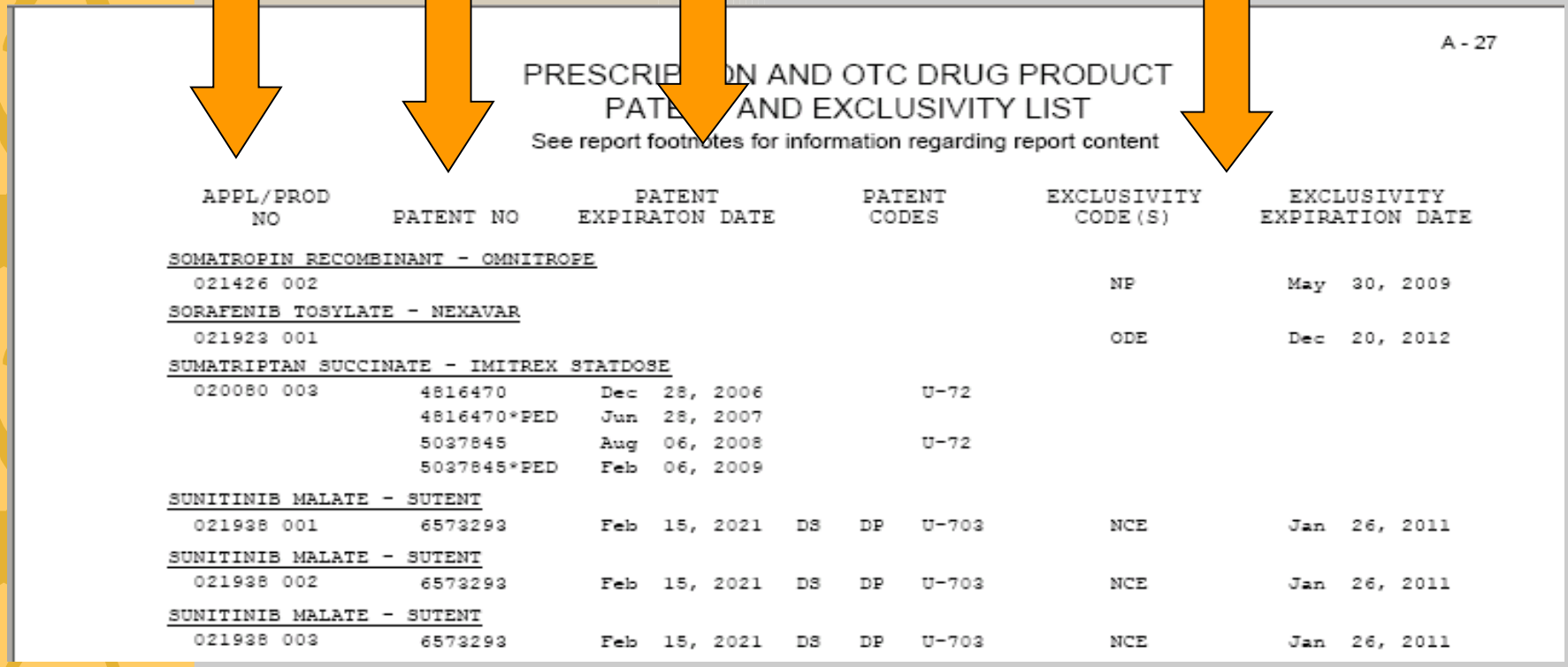
Orange Book

Lists Product Name

Patent Number

Patent Expiration Date

Exclusivity Information



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PRESCRIP ON AND OTC DRUG PRODUCT
PATE AND EXCLUSIVITY LIST

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
SOMATROPIN RECOMBINANT - OMNITROPE					
021426 002				NP	May 30, 2009
SORAFENIB TOSYLATE - NEXAVAR					
021923 001				ODE	Dec 20, 2012
SUMATRIPTAN SUCCINATE - IMITREX STATDOSE					
020080 003	4816470	Dec 28, 2006	U-72		
	4816470*PED	Jun 28, 2007			
	5037845	Aug 06, 2008	U-72		
	5037845*PED	Feb 06, 2009			
SUNITINIB MALATE - SUTENT					
021938 001	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
SUNITINIB MALATE - SUTENT					
021938 002	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
SUNITINIB MALATE - SUTENT					
021938 003	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011

"Orange Book"

- Orange Book

1) Lists:
   - Approved Drugs,
   - Discontinued Drugs
   - Provides Patent and Exclusivity Information
- Published annually with monthly cumulative supplements
- Electronic Orange Book also available

FDA Website


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Go Bookmarks 66 blocked Check Look for Map AutoFill Send to Settings
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Food
Foodborne Illness, Nutrition, Dietary Supplements...
Drugs
Prescription, Over-the-Counter, Generic...
Medical Devices
Pacemakers, Contact Lenses, Hearing Aids...
Biologics
Vaccines, Blood Products...
Animal Feed and Drugs
Livestock, Pets...
Cosmetics
Consumer Health Information
Promoting Food Safety in Puerto Rico
All Consumer Health > >
FDA NEWS
FDA Approves Nasal Influenza Vaccine for Use in Younger Children
FDA Appoints Coté to Head Orphan Products Development Office
FDA Warns Procter & Gamble about Unlawful Marketing of Product for School Children
FDA Clears for Marketing First Rapid Test to Screen for Bacterial Contamination in Blood Platelets
FDA Clears Genetic Lab Test for Warfarin Sensitivity
FDA Newsroom | Recalls, Product Safety | Product Approvals
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Counterfeit Drugs
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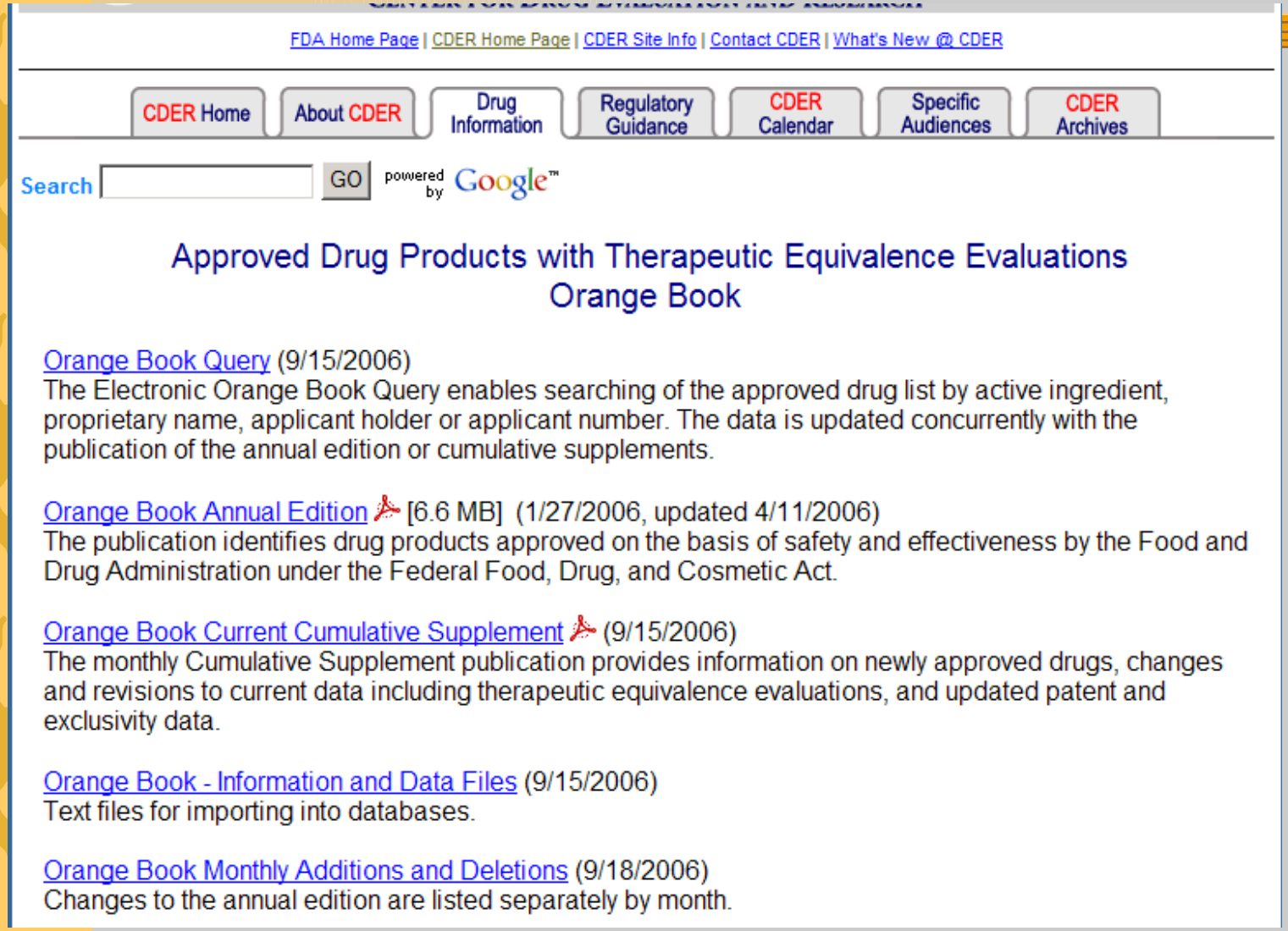
FDA Website: CDER

FDA Website: Orange Book

Electronic Orange Book

Electronic Orange Book

http://www.fda.gov/cder/orange/default.htm



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Approved Drug Products with Therapeutic Equivalence Evaluations
Orange Book

Orange Book Query (9/15/2006)
The Electronic Orange Book Query enables searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. The data is updated concurrently with the publication of the annual edition or cumulative supplements.

Orange Book Annual Edition [6.6 MB] (1/27/2006, updated 4/11/2006)
The publication identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Orange Book Current Cumulative Supplement (9/15/2006)
The monthly Cumulative Supplement publication provides information on newly approved drugs, changes and revisions to current data including therapeutic equivalence evaluations, and updated patent and exclusivity data.

Orange Book - Information and Data Files (9/15/2006)
Text files for importing into databases.

Orange Book Monthly Additions and Deletions (9/18/2006)
Changes to the annual edition are listed separately by month.

Electronic Orange Book

Errors in Orange Book

- Opportunity for generic drug companies to inform FDA that it does not believe a particular listed patent does covers the FDA-approved drug product
- FDA requests evaluation of complaint by innovator company
- Innovator company can request de-listing or respond with good-faith belief that listing is proper

Generic Drug Applications: The Process

- Generic Drug Company must certify when filing Abbreviated New Drug Application (ANDA)

1) That the drug has not been patented;
2) That the patent has already expired;
3) The date on which the patent will expire, and the generic drug will not go on the market until that date passes; or
4) That the patent is not infringed or is invalid

Referred to as paragraphs I, II, III and IV certifications

Generic Drug Applications: The Process

- Paragraph I, II, III certifications relatively straightforward
  - Existence of ANDA normally a secret until approval date
- Paragraph IV certification more complicated to administer
  - ANDA applicant must notify innovator company of its filing; must describe reasons patent will not be infringed, is invalid, or unenforceable

FDA Website Lists ANDAs with Paragraph IV Patent Certifications

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

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Paragraph IV Patent Certifications
As of October 19, 2007

Below is a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), reference listed drug (RLD), **and the date on which the first substantially complete generic drug application was submitted to the Agency (on a prospective basis beginning 3/2/04)**. The Agency will not disclose the identity of the applicant. This information will be updated twice a month and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at 301-827-5862, before making any decisions based on this information.

Any additions from the preceding list are marked with the New!! icon.

- FDA News: FDA announces measure to improve generic drug access
- Docket # 2000P-1556 Policy regarding ANDA holder confidentiality

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Acarbose	Tablets	25 mg, 50 mg and 100 mg	Precose	3/22/2005
Acetaminophen	Extended-release Tablets	650 mg	Tylenol	
Acetaminophen/ Aspirin/ Caffeine	Tablets	250 mg/250 mg/ 65 mg	Excedrin (migraine)	
Acetaminophen and Tramadol	Tablets	325 mg/ 37.5 mg	Ultracet	

Tentative Approvals are also Posted

Generic Drug Applications: The Process

- Paragraph IV Certification
  - Innovator has 45-days after receipt of notice to file an infringement suit; the submission to FDA of paragraph IV certification in an ANDA creates infringement for purposes of federal court jurisdiction
  - If lawsuit filed FDA approval is stayed for 30-months; at end of period FDA issues tentative approval
  - Most ANDA applicants await resolution of the litigation before going to market to avoid liability for damages

Patent Linkage: Benefits

- Benefits of patent information:
  - Allows Generic Drug companies to review patent information to determine:
    - When Patent Expires- Generic Drug Company Allowed to use Patented Invention after patent expires
    - What the Patent Covers
  - With information about what patents cover drug product, generic drug companies can more quickly address issue of whether patent is infringed by a competitor's use of a specific drug product

Patent Linkage: Benefits

- The system reduces wasteful and unnecessary patent infringement litigation by:
  - (1) requiring generic drug companies to assess whether their drug product is subject to a patent prior to seeking drug approval; and
  - (2) acting as a safeguard for patent rights by preventing potential patent violations.

Patent Linkage: Benefits

- An adequate linkage system also increases the efficiency and productivity of the research and development sector by:
  - (1) providing transparency and predictability of the process for both the pioneer and the generic company;
  - (2) helping both sides make better and more efficient investment decisions; and
  - (3) encouraging timely redress of disputes.
- Better and more efficient investment decisions mean faster development for life saving inventions and better healthcare.

Summary

- Information about patents simple to submit to appropriate government agency
- Agency Communicates Information to the Public
- Government agency can make appropriate decisions about approving generic applications.
- Generic Companies can access information, take appropriate actions, and make better business decisions

Thank You!!