

they possess properties from both of its parental compounds, etoposide and ellipticine. They act by stabilizing the top2-DNA cleavage complex, like etoposide does, instead of inhibiting top2 catalytic activity, the mechanism by which ellipticine acts. With regard to DNA cleavage activity, azatoxins show similar activity to etoposide. In addition to acting as a top2 inhibitor, azatoxin is also a potent inhibitor of tubulin polymerization.

The anti-cancer activity of azatoxins has been validated by cell line screening. The Developmental Therapeutics Program (DTP) of the National Cancer Institute (NCI) has tested azatoxins in its tumor cell panel and established their effectiveness against disseminated leukemia and localized tumors, such as non-small cell lung and colon cancer. These results are very encouraging showing that certain azatoxin derivatives are 100 times more active than etoposide, which is the common top2 inhibitor used in chemotherapy. Azatoxins are a novel class of potent top2 and/or tubulin inhibitors that could outperform current chemotherapeutic agents.

#### Technology Description

Topoisomerase enzymes are critical for normal cell division because they prevent tangles and knots from forming during DNA replication by cleaving and religating DNA. Several compounds have been discovered that block topoisomerases and stop its ability to religate DNA resulting in an increased number of double strand DNA breaks that kill the cell. These inhibitors are especially effective against rapidly dividing malignant cells that express high levels of top2, which represents a main reason these top2 enzymes have become an important therapeutic target. The problem is that currently used drugs are limited by their toxicity, insolubility, and their susceptibility to induce drug resistance.

In an effort to produce top2 inhibitors with increased therapeutic efficiency, well established top2 inhibitors were compared by molecular modeling to produce a composite top2 inhibitor pharmacophore of the diverse inhibitors. Based on this model, azatoxin was designed as an analogue hybrid of etoposide and ellipticine. Subsequently, several modifications of azatoxin have been synthesized to generate derivatives, such as anilinoazatoxins, which have improved pharmacological profiles.

#### Market

Despite further discoveries leading to a greater understanding and treating of

cancer, it continues to be a burden to the public health. After heart disease, cancer is the most common cause of death in the United States. In 2008, it was estimated that about 565,650 Americans were expected to die of cancer. Although, the incidence of cancer has been dropping over the years, it was estimated that over 1.4 million Americans would be diagnosed with cancer in 2008.

Cancer is not only a health burden but also a financial burden to the country. The NIH estimated the overall cost of cancer in 2007 to be \$219.2 billion dollars with \$89 billion attributable to direct medical costs. It is expected that cancer will continue to be a public health problem for the foreseeable future which prompts the need for the development of new therapeutics.

Chemotherapy is still the standard approach for treating cancers even though there were high expectations that targeted therapeutics would become the preferred drugs in cancer treatment. Current topoisomerase inhibitors have demonstrated to be effective chemotherapy drugs and they continue being developed for use in combination therapy with targeted therapeutics. However, top2 inhibitors need to be improved in order to overcome their limitations. A next-generation top2 inhibitor like azatoxins has potential in meeting this need.

#### Patent Estate

The National Institutes of Health holds a substantial portfolio of patents in U.S., Europe, Canada, and Australia which claim compositions of azatoxin and its derivatives, pharmaceutical formulations, and methods of use for chemotherapy.

The portfolio includes the following issued patents:

I. United States Patent No. 5,622,960 entitled "Topoisomerase II inhibitors and therapeutic uses therefor" issued April 22, 1997 (HHS Ref. No. E-119-1992/1-US-01).

II. United States Patent No. 5,747,520 entitled "Topoisomerase II inhibitors and therapeutic uses therefor" issued May 5, 1998 (HHS Ref. No. E-119-1992/1-US-17).

III. European Patent No. 0665846 entitled "Topoisomerase II inhibitors and therapeutic uses therefor" issued July 29, 1998 (HHS Ref. No. E-119-1992/1-EP-10) validated in Austria, Belgium, Denmark, France, Germany, Great Britain, Ireland, Italy, Luxembourg, Switzerland, and The Netherlands.

IV. Canadian Patent No. 2147608 entitled "Topoisomerase II inhibitors and therapeutic uses therefor" issued

December 12, 2006 (HHS Ref. No. E-119-1992/1-CA-06).

V. Australian Patent No. 676511 entitled "Topoisomerase II inhibitors and therapeutic uses therefor" issued June 13, 1997 (HHS Ref. No. E-119-1992/1-AU-04).

#### Next Step: Teleconference

There will be a teleconference where the principal investigator, Dr. Yves Pommier, will explain this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or e-mail Samuel Bish; (301) 435-5282; [bishse@mail.nih.gov](mailto:bishse@mail.nih.gov). The NIH Office of Technology Transfer (OTT) will then e-mail you the date, time, and number for the teleconference.

Dated: April 16, 2009.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

[Docket No. USCBP-2006-0037]

#### Expansion of Global Entry Pilot Program

**AGENCY:** U.S. Customs and Border Protection; Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** U.S. Customs and Border Protection (CBP) is currently conducting an international trusted traveler pilot program, referred to as Global Entry, at seven U.S. airports. This document announces that pursuant to an arrangement between the United States and the Netherlands, CBP is expanding eligibility for participation in the Global Entry pilot to include citizens of the Netherlands who participate in Privium, an expedited travel program in the Netherlands, and who otherwise satisfy the requirements for participation in Global Entry. Currently, eligibility is limited to U.S. citizens, U.S. nationals, and U.S. lawful permanent residents (LPRs). Pursuant to this same arrangement, U.S. citizens who participate in the Global Entry pilot will have the option to also apply for participation in Privium.

**DATES:** *Effective Dates:* Applications for the Global Entry pilot are currently

being accepted from U.S. citizens, U.S. nationals, and U.S. lawful permanent residents and will be accepted for the duration of the pilot. The expansion of eligibility to qualified citizens of the Netherlands will occur on April 23, 2009. Applications will be accepted from qualified citizens of the Netherlands beginning April 23, 2009. Comments concerning this notice and all aspects of the announced pilot may also be submitted throughout the duration of the Global Entry pilot.

**ADDRESSES:** You may submit comments, identified by "USCBP-2006-0037," by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Border Security Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, Mint Annex, 799 9th Street, NW., Washington, DC 20229.

*Instructions:* All submissions received must include the agency name, document title, and docket number (USCBP-2006-0037) for this notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received go to <http://www.regulations.gov>. Submitted comments may also be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Office of Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

Applications for the Global Entry pilot are available through the Global On-Line Enrollment System (GOES) at <http://www.globalentry.gov>. Applications must be completed and submitted electronically.

**FOR FURTHER INFORMATION CONTACT:** Fiorella Michelucci, Office of Field Operations, (202) 344-2564.

**SUPPLEMENTARY INFORMATION:**

**Background**

In a notice published in the **Federal Register** (73 FR 19861) on April 11, 2008, CBP announced an international trusted traveler pilot program, then referred to as International Registered Traveler (IRT) program, which was scheduled to commence operations at three initial U.S. airports on June 10, 2008. In a subsequent notice published

in the **Federal Register** (73 FR 30416) on May 27, 2008, CBP changed the name of the pilot program from IRT to Global Entry and moved up the starting date to June 6, 2008.

The Global Entry pilot program allows for the expedited clearance of pre-approved, low-risk travelers into the United States. The initial **Federal Register** notice published on April 11, 2008 contained a detailed description of the program, the eligibility criteria and the application and selection process, and the initial airport locations: John F. Kennedy International Airport, Jamaica, New York, Terminal 4 (JFK); the George Bush Intercontinental Airport, Houston, Texas (IAH); and the Washington Dulles International Airport, Sterling, Virginia (IAD). CBP chose these initial airports due to the large numbers of travelers that arrive at those locations from outside the United States.

On August 13, 2008, in a notice published in the **Federal Register** (73 FR 47204), CBP announced that the pilot had expanded to include all terminals at JFK and four additional airports: Los Angeles International Airport, Los Angeles, California (LAX); Hartsfield-Jackson Atlanta International Airport, Atlanta, Georgia (ATL); Chicago O'Hare International Airport, Chicago, Illinois (ORD); and Miami International Airport, Miami, Florida (MIA).

**Operations**

The Global Entry pilot project allows pilot participants expedited entry into the United States at any of the designated airport locations by using automated kiosks located in the Federal Inspection Services (FIS) area of each airport. Global Entry uses fingerprint biometrics technology to verify a participant's identity and confirm his or her status as a participant.

After arriving at the FIS area, participants proceed directly to the Global Entry kiosk. A sticker affixed to the participant's passport at the time of acceptance in Global Entry will provide visual identification that the individual can be referred to the kiosk. Global Entry participants need not wait in the regular passport control primary inspection lines.

After arriving at the kiosk, participants activate the system by inserting into the document reader either a machine-readable passport or a machine-readable U.S. permanent resident card. On-screen instructions guide participants to provide fingerprints electronically. These fingerprints are compared with the fingerprint biometrics on file to validate identity and confirm that the individual is a member of the program. Participants

are also prompted to look at the camera for a digital photograph and to respond to several customs declaration questions by use of a touch-screen.

When the procedures at the kiosk have been successfully completed, participants are issued a transaction receipt. This receipt must be provided along with the passport or permanent resident card to the CBP Officer at the exit control area who will examine and inspect these documents. CBP Officers stationed in booths next to the kiosk lanes also oversee activities at the kiosk.

**Declarations**

When using the Global Entry kiosks, Global Entry participants are required to declare all articles being brought into the U.S. pursuant to 19 CFR 148.11.

If a Global Entry participant declares any of the following, the kiosk redirects that user to the head of the line at the nearest, open passport control, primary inspection station:

(a) Commercial merchandise or commercial samples, or items that exceed the applicable personal exemption amount;

(b) More than \$10,000 in currency or other monetary instruments (checks, money orders, etc.), or foreign equivalent in any form; or

(c) Restricted/prohibited goods, such as agricultural products, firearms, mace, pepper spray, endangered animals, birds, narcotics, fireworks, Cuban goods, and plants.

Global Entry participants may also be subject to further examination and inspection as determined by CBP Officers at any time during the arrival process.

For a more detailed description of the Global Entry pilot program, please refer to the April 11, 2008 **Federal Register** notice, 73 FR 19861.

**Expanded Eligibility**

Eligibility criteria for participation in the Global Entry pilot are set forth in detail in the April 11, 2008 **Federal Register** notice. To date, only U.S. citizens, U.S. nationals, and U.S. LPRs are eligible to participate in the pilot. However, as explained in the April 11, 2008 **Federal Register** notice, CBP is working with other countries to recognize comparable programs operated by these countries and, as these arrangements are finalized, CBP will expand its eligibility criteria. The notice stated that such expansions of the pilot would be announced by publication in the **Federal Register**.

### Expansion of Global Entry to Certain Citizens of the Netherlands

The United States has entered into an arrangement with the Netherlands concerning Global Entry. Pursuant to this arrangement, CBP is expanding eligibility for the Global Entry pilot. Specifically, citizens of the Netherlands who participate in Privium, an expedited travel program in the Netherlands, will now be able to apply for participation in the Global Entry pilot. In order to participate, these citizens of the Netherlands will be required to complete the on-line application, pay the non-refundable \$100 per person applicant processing fee, and satisfy all the requirements of the Global Entry pilot. Based on the terms of the arrangement reached with the Government of the Netherlands, these citizens will be permitted to participate in the Global Entry pilot only upon successful completion of a thorough risk assessment by both U.S. Customs and Border Protection and the Government of the Netherlands.

No person who is inadmissible to the United States under U.S. immigration law is eligible to participate in the Global Entry pilot. Applications from such individuals will automatically be rejected. Applications for the Global Entry pilot may also be rejected if the applicant has ever been convicted of a criminal offense, or the individual has ever been found in violation of the customs or immigration laws of the United States, or of any criminal law. Additionally, no applicant will be accepted for participation in the Global Entry pilot if CBP determines that the individual presents a potential risk for terrorism, criminality or smuggling, or if CBP cannot sufficiently determine that the applicant meets all the program eligibility criteria. CBP will be accepting applications from eligible citizens of the Netherlands beginning April 23, 2009. Additional information on eligibility will be announced at <http://www.globalentry.gov>.

The Netherlands is also a participant in the Visa Waiver Program (VWP). The VWP enables citizens and nationals from participating countries to travel to and enter the United States for business or pleasure purposes for up to 90 days without obtaining a visa.<sup>1</sup> VWP travelers are now required to obtain a travel

<sup>1</sup> Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRPTA), 118 Stat. 3638, as amended by section 565 of the Consolidated Appropriations Act, 2008, 121 Stat. 1844, codified at 8 U.S.C. 1365b, directs the Secretary to establish an international registered traveler program in coordination with US-VISIT, other prescreening initiatives, and the Visa Waiver Program. See 8 U.S.C. 1365b(k)(3).

authorization via ESTA (Electronic System for Travel Authorization) prior to traveling to the United States under the VWP. ESTA is accessible online at <https://esta.cbp.dhs.gov>. The ESTA requirements will continue to be applicable to Global Entry applicants who are VWP travelers. Global Entry applicants from the Netherlands who wish to travel to the United States under the VWP who have not already received a travel authorization via ESTA will be able to do so as part of the Global Entry application and enrollment process. During the Global Entry enrollment and interview phase the applicant will be asked whether he or she is in possession of an ESTA authorization number. If not in possession of an ESTA authorization number, the applicant will be asked questions from which it can be determined whether the applicant is VWP-eligible, and a determination regarding ESTA authorization will be made.

All other aspects of the program as described in the April 11, 2008 notice are still in effect.

#### U.S. Citizen Participation in Privium

Pursuant to the reciprocal arrangement with the Government of the Netherlands, U.S. citizens who participate in the Global Entry pilot will have the option to also apply for participation in Privium. Privium is an automated border passage system in the Netherlands that provides expedited entry and exit at Amsterdam Airport Schiphol. It uses iris scans to provide quick and secure biometric confirmation of a traveler's identity. Enrollment includes an eligibility assessment by the Dutch border police. Upon a positive determination of eligibility, pictures of each iris are taken and stored on a personalized smart card. Upon entry and exit, Privium members place their Privium smart card into a reader and a passport validity check is performed with the Dutch authorities and valid membership is verified. The individual's iris information is then compared against the iris information stored on the card. This border passage process takes approximately twelve seconds.

Additional fees and information sharing beyond CBP's Global Entry requirements are needed for U.S. citizens who wish to participate in Privium through Global Entry. If approved, U.S. citizens would be able to take advantage of expedited travel into, and out of, the Netherlands at Amsterdam Airport Schiphol. More information about how to apply for Privium membership is available at <http://www.globalentry.gov>.

Dated: April 16, 2009.

Susan T. Mitchell,

Acting Assistant Commissioner, Office of Field Operations.

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### DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5285-N-14]

#### Notice of Proposed Information Collection: Comment Request; FHA Insured Title I Property Improvement and Manufactured Home Loan Programs

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date:* June 22, 2009.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410; e-mail or telephone (202) 402-8048.

**FOR FURTHER INFORMATION CONTACT:** Margaret Burns, Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708-2121 (this is not a toll free number) for copies of the proposed forms and other available information.

**SUPPLEMENTARY INFORMATION:** The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have