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Paperwork Reduction Act Burden Statement

(5) A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

Definitions

(v) For the purposes of this AD, an EGT above redline is a confirmed over-temperature indication that is not a result of EGT system error.

(w) For the purposes of this AD, a shift in the smoothed EGT trending data is a shift in a rolling average of EGT that can be confirmed by a corresponding shift in the trending of fuel flow or fan speed/core speed (N1/N2) relationship. You can find further guidance about evaluating EGT trend data in GE Company Service Rep Tip 373 "Guidelines For Parameter Trend Monitoring."

Previous Credit

(x) A borescope inspection performed before the effective date of this AD using AD 2010-06-15, Amendment 39-16240 (75 FR 12661, March 17, 2010) or AD 2010-12-10, Amendment 39-16331 (75 FR 32649, June 9, 2010) within the last 75 cycles, satisfies the initial borescope inspection requirement in paragraph (f)(1) of this AD.

(y) A UI performed before the effective date of this AD using GE SB No. CF6-50-SB 72-1312, dated August 9, 2010 or GE SB No. CF6-50-SB 72-1312 Revision 1, dated October 18, 2010, satisfies the inspection requirement in paragraph (n) of this AD.

(z) An engine core vibration survey performed before the effective date of this AD using GE SB No. CF6-50-SB 72-1313, dated August 9, 2010 or GE SB No. CF6-50-SB 72-1313 Revision 1, dated October 18, 2010, within the last 350 cycles, satisfies the initial survey requirement in paragraph (o) of this AD.

Alternative Methods of Compliance (AMOCs)

(aa) AMOCs previously approved for AD 2010-06-15, Amendment 39-16240 (75 FR 12661, March 17, 2010) are not approved for this AD. However, AMOCs previously approved for AD 2010-12-10, Amendment 39-16331 (75 FR 32649, June 9, 2010) are approved for this AD.

(bb) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(cc) Contact Tomasz Rakowski, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7735; fax: 781-238-7199; e-mail: tomasz.rakowski@faa.gov, for more information about this AD.

Material Incorporated by Reference

(dd) You must use GE Service Bulletin No. CF6-50-SB 72-1312, Revision 1, dated October 18, 2010, to do the ultrasonic inspections required by this AD.

(1) The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) Contact General Electric Company, GE-Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215, telephone (513) 552-3272; fax (513) 552-3329; e-mail: geae.aoc@ge.com for a copy of this service information.

(3) You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on January 14, 2011.

Peter A. White,

Acting Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011-2387 Filed 2-3-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 516

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Masitinib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect conditional approval of an application for a new animal drug intended for a minor use filed by AB Science. The application for conditional approval

provides for the veterinary prescription use of masitinib mesylate tablets in dogs.

DATES: This rule is effective February 4, 2011.

FOR FURTHER INFORMATION CONTACT: Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8322, e-mail: lisa.troutman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: AB Science, 3 Avenue George V, 75008 Paris, France, filed an application for conditional approval (141-308) that provides for veterinary prescription use of KINAVET-CA1 (masitinib mesylate) Tablets for the treatment of recurrent (post-surgery) or nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids. In accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), this drug is conditionally approved as of December 15, 2010, and the regulations in part 516 (21 CFR part 516) are amended by adding new § 516.1318.

In addition, AB Science has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support conditional approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

KINAVET-CA1 (masitinib mesylate) Tablets for the intended uses conditionally approved by FDA under application number 141-308 qualifies for 7 years of exclusive marketing rights beginning on the date of conditional approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the FD&C Act (21 U.S.C. 360ccc-2(c)) because it has

been declared a designated new animal drug by FDA under section 573(a) of the FD&C Act.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 516 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:
Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "AB Science"; and in the table in paragraph (c)(2), numerically add an entry for "052913" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *	
(c) * * *	
(1) * * *	
Firm name and address	Drug labeler code
* * * * *	* * *
AB Science, 3 Avenue George V, 75008 Paris, France	052913
* * * * *	* * *
(2) * * *	
Drug labeler code	Firm name and address
* * * * *	* * * * *
052913	AB Science, 3 Avenue George V, 75008 Paris, France.
* * * * *	* * * * *

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 4. Add § 516.1318 to subpart E to read as follows:

§ 516.1318 Masitinib.

(a) *Specifications.* Each tablet contains 50 or 150 milligrams (mg) masitinib mesylate.

(b) *Sponsor.* See No. 052913 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 12.5 mg/kilograms (5.7 mg/lb) of body weight daily.

(2) *Indications for use.* For the treatment of recurrent (post-surgery) or nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

Dated: January 28, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
 [FR Doc. 2011–2519 Filed 2–3–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Restricted Area, Potomac River, Marine Corps Base Quantico, Quantico, VA

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is amending its regulations to establish a restricted area in the waters of the Potomac River extending offshore from the Marine Corps Air Facility (MCAF) at Marine Corps Base Quantico (MCB Quantico), located in Quantico, Virginia. The restricted area will address current security needs at MCB Quantico, including the protection of military assets at MCAF which includes the Presidential Helicopter Squadron (HMX–1). The restricted area will also protect public health by preventing vessels from disturbing a planned

environmental remediation area that is located to the northeast of MCAF.

DATES: *Effective date:* March 7, 2011.

ADDRESSES: Headquarters, U.S. Army Corps of Engineers, Operations and Regulatory Community of Practice, 441 G Street, NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or by e-mail at *david.b.olson@usace.army.mil* or Mr. Steve Elinsky, U.S. Army Corps of Engineers, Baltimore District, Regulatory Branch, at 410–962–4503 or by e-mail at *steve.elinsky@usace.army.mil*.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps is amending its regulations to establish a restricted area in the waters of the Potomac River extending offshore from the MCAF at MCB Quantico, located in Quantico, Virginia. The restricted area will address current security needs at MCB Quantico, including the protection of military assets at MCAF which includes the Presidential Helicopter Squadron (HMX–1). The restricted area will also protect public health by preventing vessels from disturbing a planned environmental remediation area that is located to the northeast of MCAF.

The proposed rule was published in the August 31, 2010, edition of the **Federal Register** (75 FR 53264) and the docket number was COE–2010–0032. In September 2010, the Corps Baltimore and Norfolk districts issued public notices soliciting comments on the proposal from all known interested parties. The districts received three comments.

One commenter indicated that this action does not require essential fish habitat (EFH) conservation measures to protect EFH. Another commenter said that the proposed undertaking would have no effect on historic resources in Maryland. One commenter stated that the establishment of the restricted area would not impact recreation nor would it adversely affect any documented state-listed plant or animal species in Virginia.

None of these comments warrant changes to the rule text. However, to provide clarity in the final rule, the following changes were made to the rule text:

1. The provisions concerning the timing of the restrictions stated in