Technical Note: Parity bits are not included in the key length.

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Dated: September 15, 2011.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2011–24229 Filed 9–20–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2011-D–0633]

Revised Guidance on Marketed Unapproved Drugs; Compliance Policy Guide Sec. 440.100; Marketed New Drugs Without Approved NDAs or ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of compliance policy guide.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 440.100). CPG 440.100 describes how FDA intends to exercise its enforcement discretion with regard to drug products marketed in the United States that do not have required FDA approval for marketing. CPG 440.100 has been revised to state that the enforcement priorities and potential exercise of enforcement discretion discussed in the CPG apply only to unapproved new drug products that are being commercially used or sold as of September 19, 2011. All unapproved new drugs introduced onto the market after that date are subject to immediate enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in CPG 440.100.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002, 301–796–3349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs''. This CPG is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This CPG is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because, in light of the fact that revised CPG 440.100 establishes the date after which the enforcement priorities and potential exercise of enforcement discretion discussed in it do not apply to newly introduced unapproved drugs, delayed implementation of revised CPG 440.100 would provide an incentive for manufacturers to rush new unapproved drugs to market during the comment and finalization period, in order to be subject to enforcement priorities that may be perceived as more advantageous to extended marketing of illegal, unapproved drug products. The potential increase in marketing of new unapproved drugs raises public health concerns; because unapproved drug products have not been approved by FDA for safety, effectiveness, and quality, patients may be at greater risk when using unapproved drug products than when using FDA-approved drug products. In light of the concerns about potential increased marketing of new unapproved drugs, FDA has determined that it is not appropriate to seek comment before implementing revised CPG 440.100. Although CPG 440.100 is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

Under the Federal Food, Drug, and Cosmetic Act, drug products that require approval must obtain that approval prior to introduction into interstate commerce (*see* 21 U.S.C. 355). Manufacturers and distributors of products that enter the market without complying with these long-standing statutory requirements are acting in violation of the law. In June 2006, FDA announced a new drug safety initiative to remove unapproved drugs from the market. As part of the Unapproved Drugs Initiative, FDA issued a final CPG entitled ''Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 440.100) (*see* 71 FR 33466, June 9, 2006). CPG 440.100 describes how FDA intends to exercise its enforcement discretion regarding currently marketed unapproved new drugs. CPG 440.100 describes six categories of unapproved drug products that are the Agency's highest enforcement priorities, and the circumstances in which the Agency intends to bring enforcement actions consistent with those priorities. FDA has initiated 17 actions against unapproved new drugs under the Unapproved Drugs Initiative and engaged in significant outreach to manufacturers, distributors, consumers and prescribers under this Initiative, resulting in the removal of over a thousand unapproved new drugs from the market (see *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm*).

Despite both the long-standing statutory requirement that new drugs must obtain approval prior to marketing (21 U.S.C. 355) and FDA's outreach efforts under the Marketed Unapproved Drugs Initiative, FDA is aware that unapproved new drugs have continued to come onto the market after the issuance of the 2006 CPG. In some cases, these unapproved new drugs come onto the market to compete with other unapproved new drugs that are already on the market. In other cases, unapproved new drugs are introduced to the market when a manufacturer perceives that there may be an ''opportunity'' to gain a share of the market after actions taken by FDA, including enforcement actions that remove similar unapproved new drugs from the market. In either case, FDA must expend additional scarce resources to address unapproved products in situations where manufacturers and distributors have had ample notice that the products they are introducing onto

the market cannot be legally marketed without approval.

To address this situation, FDA is revising CPG 440.100 to make clear that unapproved new drugs introduced onto the market after September 19, 2011 are subject to enforcement action at any time, without prior notice and without regard to the enforcement priorities set forth in CPG 440.100 for unapproved new drugs marketed prior to September 19, 2011. The revision to CPG 440.100 excludes from the enforcement priorities set forth in the guidance the manufacture and marketing of newly introduced unapproved drugs.

This guidance represents the Agency's current thinking on its enforcement priorities with respect to new drugs marketed without approved new drug applications or abbreviated new drug applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24316 Filed 9–19–11; 12:30 pm]

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN)is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS FORT WORTH (LCS 3) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective September 21, 2011 and is applicable beginning September 8, 2011.

FOR FURTHER INFORMATION CONTACT: Lieutenant Jaewon Choi, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone number: 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS FORT WORTH (LCS 3) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the height of the forward masthead light above the hull; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light, and the horizontal separation between the forward and after masthead lights; Annex I, paragraph 2(i)iii, pertaining to the spacing of the three lights in the task light array; Rule 27, paragraph (b)i, pertaining to the verticality of the three all-round task lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

For the reasons set forth in the preamble, the Navy amends part 706 of title 32 of the CFR as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended as follows:

■ A. In Table One, add, in alpha numerical order by vessel number, an entry for USS FORT WORTH (LCS 3);

■ B. In Table Four, under paragraph 22 add, in alphanumerical order by vessel number, an entry for USS FORT WORTH (LCS 3);

■ C. In Table Four, under paragraph 23 add, in alphanumerical order by vessel number, an entry for USS FORT WORTH (LCS 3); and

■ D. In Table Five add, in alpha numerical order by vessel number, an entry for USS FORT WORTH (LCS 3).

The additions read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

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