about reporting in this survey, either by sending them a report form or by written inquiry, must respond pursuant to § 806.4. This may be accomplished by:

(1) Filing the properly completed BE–12 report—Form BE–12(LF), Form BE–12(SF), Form BE–12 Mini, or Form BE–12 Bank, by May 31, 2008, as required;

(2) Completing and returning the Form BE–12 Claim for Not Filing by May 31, 2008; or

(3) Certifying in writing, by May 31, 2008, to the fact that the person is not a U.S. affiliate of a foreign person and not subject to the reporting requirements of the BE–12 survey.

(b) Who must report. A BE–12 report is required for each U.S. affiliate, that is, for each U.S. business enterprise in which a foreign person (foreign parent) owned or controlled, directly or indirectly, 10 percent or more of the voting securities in an incorporated U.S. business enterprise, or an equivalent interest in an unincorporated U.S. business enterprise, at the end of the business enterprise's fiscal year that ended in calendar year 2007. A BE–12 report is required even if the foreign person's ownership interest in the U.S. business enterprise was established or acquired during the 2007 reporting year. Beneficial, not record, ownership is the basis of the reporting criteria.

(c) Forms to be filed. (1)—Form BE–12(LF) (Long Form) must be completed by a U.S. affiliate that was majority-owned by one or more foreign parents (for purposes of this survey, a ''majority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate exceeds 50 percent), if:

(i) It is not a bank and is not owned directly or indirectly by a U.S. bank holding company or financial holding company, and

(ii) On a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the following three items for the U.S. affiliate (not just the foreign parent's share), was greater than $175 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2007:

(A) Total assets (do not net out liabilities);

(B) Sales or gross operating revenues, excluding sales taxes; or

(C) Net income after provision for U.S. income taxes.

(2) Form BE–12(SF) (Short Form) must be completed by a U.S. affiliate if:

(i) It is not a bank and is not owned directly or indirectly by a U.S. bank holding company or financial holding company, and

(ii) On a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1)(ii) of this section for a majority-owned U.S. affiliate (not just the foreign parent's share), was greater than $40 million (positive or negative) but none of these items was greater than $175 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2007.

(iii) On a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1)(ii) of this section for a minority-owned U.S. affiliate (not just the foreign parent's share), was greater than $40 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2007. (A ''minority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate is 50 percent or less.)

(3) Form BE–12 Mini must be completed by a U.S. affiliate if:

(i) It is not a bank, and is not owned directly or indirectly by a U.S. bank holding company or financial holding company, and

(ii) On a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, none of the three items listed in paragraph (c)(1)(ii) of this section for a U.S. affiliate (not just the foreign parent's share), was greater than $40 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2007.

(4) Form BE–12 Bank must be completed by a U.S. affiliate if:

(i) The U.S. affiliate is a bank. For purposes of the BE–12 survey, a ''bank'' is a business entity engaged in deposit banking or closely related functions, including commercial banks, Edge Act corporations engaged in international or foreign banking, U.S. branches and agencies of foreign banks whether or not they accept domestic deposits, savings and loans, savings banks, bank holding companies and financial holding companies under the Gramm-Leach-Bliley Act, including all subsidiaries or units of a bank holding company or financial holding company, and

(ii) On a fully consolidated basis any one of the three items listed in paragraph (c)(1)(ii) of this section for a U.S. affiliate (not just the foreign parent's share), was greater than $15 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2007.

(5) Form BE–12 Claim for Not Filing will be provided for response by persons that are not subject to the reporting requirements of the BE–12 survey but have been contacted by BEA concerning their reporting status.

(d) Aggregation of real estate investments. All real estate investments of a foreign person must be aggregated for the purpose of applying the reporting criteria. A single report form must be filed to report the aggregate holdings, unless written permission has been received from BEA to do otherwise. Those holdings not aggregated must be reported separately on the same type of report that would have been required if the real estate holdings were aggregated.

(e) Due date. A fully completed and certified Form BE–12(LF), BE–12(SF), BE–12 Mini, BE–12 Bank, or Form BE–12 Claim for Not Filing is due to be filed with BEA not later than May 31, 2008.

§ 806.18 OMB control numbers assigned to the Paperwork Reduction Act.

(a) *Purpose.* This section complies with the requirements of section 3507 (f) of the Paperwork Reduction Act (PRA) which requires agencies to display a current control number assigned by the Director of OMB for each agency information collection requirement.

(b) *Display.*

15 CFR section where identified and described	Current OMB control No.
806.1 through 806.17	0608–0020 0024 0032 0004 0035 0030 0009 0023 0034 0042 0053

[FR Doc. E7–24972 Filed 12–21–07; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect a change of sponsor's name from Altana, Inc., to Nycomed US, Inc.

DATES: This rule is effective December 26, 2007.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Altana, Inc., 60 Baylis Rd., Melville, NY 11747, has informed FDA that it has changed its name to Nycomed US, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

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 in 21 CFR Part 510

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

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is 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), remove the entry for ''Altana, Inc.'' and alphabetically add a new entry for ''Nycomed US, Inc.''; and in the table in paragraph (c)(2), revise the entry for ''025463'' 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
* * * * *	
Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747.	025463
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
025463	Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747
* * * * *	

Dated: December 12, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–24974 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1312

[Docket No. DEA–276F]

RIN 1117–AB00

Reexportation of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: The Controlled Substances Export Reform Act of 2005 amended the Controlled Substances Import and Export Act to provide authority for the Drug Enforcement Administration (DEA) to authorize the export of controlled substances from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied. DEA is amending its regulations to implement the new legislation.

DATES: *Effective Date:* This rule is effective January 25, 2008.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

The Controlled Substances Export Reform Act of 2005 (Pub. L. 109–57) was enacted on August 2, 2005. The Act amends the Controlled Substances Import and Export Act (CSIEA) to provide authority for the Attorney General (and DEA, by delegation) [1] to authorize the export of controlled substances in schedules I and II, and narcotic controlled substances in schedules III and IV, from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied.

Previously under the CSIEA (prior to the 2005 legislation), there were no circumstances in which it was permissible to export a controlled substance in schedules I and II, or a narcotic controlled substance in schedules III and IV, for the purpose of reexport to another country. Such controlled substances could lawfully be exported only to the immediate country where they would be consumed.

The Controlled Substances Export Reform Act requires the following:

> Notwithstanding [21 U.S.C. 953] subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:
>
> (1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the 'first country') and the country to which the controlled substance is exported from the first country (referred to in this subsection as the 'second country') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.
>
> (2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.
>
> (3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.
>
> (4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—
>
> (A) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and
>
> (B) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.
>
> (5) The controlled substance will not be exported from the second country.
>
> (6) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

[1] 28 CFR 0.100(b).