provisions. FDA received two letters in response to the notice, each containing one or more comments. One comment suggested that FDA make the voluntary cosmetic registration program mandatory. FDA responds that it has no statutory authority to require mandatory cosmetic product reporting. The remaining comments received were not responsive to the comment request on the four specified aspects of the collection of information. These non-responsive comments will not be addressed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.1 through 720.4 (new submissions)	FDA 2512[2]	141	31	4,371	.33	1,442
720.4 and 720.6 (amendments)	FDA 2512	109	7	763	.17	130
720.3, 720.6 (notices of discontinuance)	FDA 2512	55	41	2,255	.1	226
720.8 (requests for confidentiality)		1	1	1	1.5	1.5
Total						1,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term ''Form FDA 2512'' refers to both the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at *http://www.cfsan.fda.gov/~dms/cos-regn.html*.

The estimated number of respondents is based on submissions received from fiscal years 2005 to 2007. The estimated time required for each submission is based upon information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms FDA 2512, 2512a, and 2514. The increase in total annual responses is due to increased participation by cosmetic companies, because of a renewed industry commitment to the program, and implementation of the online filing system on December 1, 2005. The decrease in hours per response is due to the ease of online filing.

Dated: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29685 Filed 12–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0629]

Draft Guidance for Industry on Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches.'' This draft guidance is intended to inform pharmaceutical manufacturers of the agency's thinking regarding genotoxic and carcinogenic impurities in drug substances and drug products, including biologic products that are regulated by the Center for Drug Evaluation and Research (CDER), and to provide recommendations on how to evaluate the safety of these impurities during clinical development and for marketing applications. This draft guidance, when finalized, will clarify FDA's additional testing and exposure threshold recommendations for situations in which genotoxic or carcinogenic impurities are present. This draft guidance addresses synthetic impurities and degradants in drug substances, but does not otherwise address the genotoxicity or carcinogenicity of actual drug substances or intended drug product ingredients. This draft guidance also applies to known starting materials or anticipated reaction products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft 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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993–0002, 301–796–0175.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches.'' This draft guidance is intended to inform pharmaceutical manufacturers of the agency's thinking regarding genotoxic and carcinogenic impurities in drug substances and drug products, including biologic products regulated by CDER,

and to provide recommendations on how to evaluate the safety of these impurities. Genotoxic compounds, because of their ability to induce genetic mutations, chromosomal breaks, and/or chromosomal rearrangements, have the potential for being carcinogenic to humans.

Regulatory issues related to the presence of genotoxic or carcinogenic impurities have arisen with greater frequency because of enhanced technological capability in identifying impurities and an increased focus on their potential for negatively affecting human health. FDA guidance documents that address issues related to impurities and residual solvents include the following International Conference on Harmonisation (ICH) guidances for industry: ''Q3A(R2) Impurities in New Drug Substances,'' ''Q3B(R2) Impurities in New Drug Products,'' and ''Q3C(R3) Impurities: Guideline for Residual Solvents.'' However, these ICH guidances do not fully address situations in which genotoxic or carcinogenic impurities are present.

This draft guidance describes acceptable approaches for initially evaluating the genotoxic potential of impurities as well as approaches for handling impurities with known genotoxic or carcinogenic potential. These approaches include prevention of the impurity formation, reduction of the impurity level to an acceptable threshold, or additional characterization of the genotoxic and carcinogenic risk. The draft guidance also discusses various factors that should be considered in the overall risk assessment based on the drug indication, duration of use, and the clinical development stage.

FDA has developed this draft guidance because these types of impurities are being identified more frequently and because FDA has received a number of questions from industry regarding acceptable approaches.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommended approaches for genotoxic and carcinogenic impurities in drug substances and products. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB Control Numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29674 Filed 12–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0626]

Draft Guidance for Industry on Bioequivalence Recommendation for Vancomycin HCl; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendation for Vancomycin HCl.'' The recommendation provides specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for vancomycin HCl capsules.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft 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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm*. As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of the agency's draft BE recommendation for vancomycin HCl capsules.

Vancocin (vancomycin HCl) oral capsules, approved by FDA in April 1986, are indicated for the treatment of