seeks a determination that DELALUTIN (hydroxyprogesterone caproate) injection was not withdrawn for reasons of safety or efficacy. FDA has reviewed the information submitted by petitioner and has independently evaluated relevant literature and data for adverse event reports for DELALUTIN (hydroxyprogesterone caproate) injection. Based on its evaluation, FDA does not consider this information to indicate that DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, was withdrawn for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA determines that DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

In considering whether to file an ANDA for this drug product, future applicants should be advised that they may not be able to obtain DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, for bioequivalence testing because the product has not been commercially available for a number of years. An ANDA applicant who is unable to obtain DELALUTIN (hydroxyprogesterone caproate) injection, 125 mg/mL and 250 mg/mL, for bioequivalence testing should contact the Office of Generic Drugs for a determination of what showing is necessary to satisfy the requirements of section 505(j)(2)(A)(iv) of the act. If an ANDA is approved without a showing of bioequivalence, the approved product will not be considered therapeutically equivalent (i.e., granted an AB rating) in the Orange Book.

Dated: June 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15416 Filed 6–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0283]

Draft Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes Reportable in Annual Reports; 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 "CMC Postapproval Manufacturing Changes Reportable in Annual Reports." This draft guidance provides recommendations to holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding the types of changes that may be reported in annual reports. Specifically, the draft guidance describes chemistry, manufacturing, and controls (CMC) postapproval manufacturing changes that FDA has determined will likely present minimal potential to have adverse effects on product quality and, therefore, may be reported by applicants in an annual report. (The draft guidance excludes positron emission tomography (PET) drug 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 either electronic or written comments on the draft guidance by September 23, 2010.

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 4178, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "CMC Postapproval Manufacturing Changes Reportable in Annual Reports." This draft guidance provides recommendations to holders of NDAs and ANDAs regarding the types of CMC postapproval manufacturing changes that FDA has determined will likely present minimal potential to have adverse effects on product quality, and therefore, may be reported by applicants in an annual report under § 314.70 (21 CFR 314.70).

In its September 2004 final report, "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century—A Risk-Based Approach" (Pharmaceutical Product Quality Initiative, *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/ucm137175.htm*), FDA stated that to keep pace with the many advances in quality management practices in manufacturing and to enable the agency to more effectively allocate its limited regulatory resources, FDA would implement a cooperative, risk-based approach for regulating pharmaceutical manufacturing. As part of this approach, FDA determined that to provide the most effective public health protection, its CMC regulatory review should be based on an understanding of product risk and how best to manage this risk.

The number of CMC manufacturing supplements for NDAs and ANDAs has continued to increase over the last several years. In connection with FDA's Pharmaceutical Product Quality Initiative and its risk-based approach to CMC review, FDA has evaluated the types of changes that have been submitted in CMC postapproval manufacturing supplements and determined that many of the changes being reported present very low risk to the quality of the product and do not need to be submitted in supplements.

Based on this recent evaluation, FDA developed a list (attached as an appendix to the draft guidance) to provide current recommendations to companies regarding which postapproval manufacturing changes for NDAs and ANDAs may be considered to have a minimal potential for an adverse effect on the identity, strength, quality, purity, or potency of the drug product and, therefore, may be classified as a change reportable in an annual report (e.g., notification of a change after implementation) rather than in a supplement.

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 CMC postapproval manufacturing changes reportable in annual reports for NDAs and ANDAs. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: CMC Postapproval Manufacturing Changes Reportable in Annual Reports.

Description of Respondents: Respondents to this collection of information are applicants of approved NDAs and ANDAs.

Burden Estimate: FDA is requesting public comment on estimates of annual submissions from these respondents, as required by § 314.70 and §§ 314.71, 314.81(b)(2), and 314.97 (21 CFR 314.71, 314.81(b)(2), and 314.97) and described in this draft guidance. Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application. Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252). Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA approval. Section 314.98(c) requires annual reports and other postmarketing reports for ANDAs. The estimate for annual reports for ANDAs is included under § 314.81(b)(2). Other postmarketing reports under § 314.98(c) are not implicated by this notice.

The draft guidance describes our current thinking on the interpretation of these requirements. Part of the intent for this draft guidance is to reduce the burden of reporting some manufacturing changes. Currently, for postapproval changes considered to be major, applicants of NDAs and ANDAs must submit and receive FDA approval of a supplement before the product made with the manufacturing change is distributed. If a change is considered to be moderate, an applicant must submit a supplement at least 30 days before the product is distributed or, in some cases, submit a supplement at the time of distribution. If a change is considered to be minor, an applicant may proceed with the change, but must notify FDA of the change in an annual report. When a change is approved via a supplemental application, these changes currently also must be reported in the annual report. The draft guidance describes the types of postapproval changes that applicants of NDAs and ANDAs currently submit in supplements to NDAs or ANDAs but that, under the draft guidance, may now be reported only in annual reports and do not need prior FDA approval. As a result, applicants would no longer need to submit supplements for such changes.

FDA currently has OMB approval for the collection of information entitled, "Application for Food and Drug Administration Approval to Market a New Drug" (OMB Control Number 0910–0001). This collection of information includes all information requirements imposed by the regulations under part 314 (21 CFR part 314) on applicants who apply for approval of an NDA or ANDA to market or change an approved application. In particular, among other things, this collection of information includes: (1) The submission of supplements to FDA for certain changes to an approved application in accordance with §§ 314.70 and 314.71; (2) the submission of annual reports to FDA (Form FDA 2252) in accordance with § 314.81(b)(2); (3) the submission of supplements to an approved ANDA for changes that require FDA approval; and (4) other postmarketing reports for ANDAs in accordance with § 314.98(c), of which the estimate for annual reports is included under § 314.81(b)(2). Therefore, this information collection includes the supplements to NDAs and ANDAs and the annual reports for NDAs and ANDAs that are described in the draft guidance.

Under the applicable regulations and the draft guidance, the following change to the current approval by OMB under the PRA is estimated: Supplements to NDAs under §§ 314.70 and 314.71 and supplements to ANDAs under § 314.97. Although the submission of supplements to NDAs and ANDAs is approved under OMB Control Number 0910–0001, the total number of supplements submitted per year is estimated to be reduced based on the recommendations in the draft guidance because certain changes submitted as supplements would now be submitted in annual reports. Therefore, for such changes, the information collection with respect to the submission of supplements will be reduced. Because the number of supplements per year is estimated to be reduced, the total number of hours for preparing supplements is also estimated to be reduced.

Based on FDA's knowledge of supplements and annual reports to NDAs and ANDAs, as well as the agency's familiarity with the time needed to prepare supplements and annual reports, our estimates for this information collection are as follows: The total number of supplements submitted per year is estimated to be reduced based on the recommendations in the draft guidance. Based on the number of CMC manufacturing supplements received for NDAs and ANDAs during 2008, FDA estimates that it will receive annually approximately 800 responses under §§ 314.70 and 314.71 for NDAs and approximately 2,075 responses under § 314.97 for ANDAs. The number of annual frequencies per response will decrease accordingly. FDA estimates that approximately the same number of respondents will submit responses under §§ 314.70, 314.71, and 314.97 and each response will take approximately the same amount of time to prepare as in the information collection currently approved under OMB Control Number 0910–0001.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
314.70 and 314.71	281 (same as currently approved)	2.85	800	150 (same as currently approved)	120,000
314.97	215 (same as currently approved)	9.65	2,075	80 (same as currently approved)	166,000
Total Hours					286,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information collection is 286,000 hours.

IV. 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: June 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15415 Filed 6–24–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A New Class of Antibiotics: Natural Inhibitors of Bacterial Cytoskeletal Protein FtsZ To Fight Drug-Susceptible and Multi-Drug Resistant Bacteria

Description of Invention: The risk of infectious diseases epidemic has been alarming in recent decades. This is not only because of the increase incident of so-called "super bugs," but also because of the scarce number of potential antibiotics in the pipeline. Currently, the need for new antibiotics is greater than ever! The present invention by the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), part of the National Institute of Health (NIH), address this urgent need. The invention is a new class of chrysophaentin antibiotics that inhibit the growth of broad-spectrum, drug-susceptible, and drug-resistant bacteria.

Derived from the yellow algae *Chrysophaeum taylori,* the inventor has extracted 8 small molecules of natural products and tested for antimicrobial activity against drug resistant bacteria, methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus faecalis* (VRE), as well as other drug susceptible strains. Structurally, the molecules represent a new class of antibiotic that also likely work through a distinct mechanism of action from that of current antibiotics, which is key for the further development of antibiotics that inhibit drug-resistant strains.

The bacterial cytoskeletal protein FtsZ is a GTPase and has structural homology to the eukaryotic cytoskeletal protein tubulin, but lacks significant sequence similarity. FtsZ is essential for bacterial cell division. It is responsible for Z-ring assembly in bacteria, which leads to bacterial cell division. Experiments show that the disclosed compounds are competitive inhibitors of GTP binding to FtsZ, and must bind in the GTP-binding site of FtsZ. Inhibition of FtsZ stops bacterial cell division and is a validated target for new antimicrobials. FtsZ is highly conserved among all bacteria, making it a very attractive antimicrobial target.

Applications:

- Therapeutic potential for curing bacterial infections *in vivo,* including for clinical and veterinary applications.
- Antiseptics in hospital sittings.
- Since FtsZ is structurally similar, but do not share sequence homology to eukaryotic cytoskeletal protein tubulin, these compounds may have antitumor properties against some cancer types or cell lines.

Advantages:

- Structurally distinct antimicrobial compounds.
- Attack newly validated antibacterial targeted protein FtsZ.
- These compounds have a unique mechanism of action which inhibit FtsZ by inhibiting FtsZ GTPase activity.
- Inhibit drug-susceptible and drug-resistant bacteria.

Development Status: