FDA also provides recommendations on how to prioritize reporting when regulatory timelines cannot be met due to limited resources during a pandemic, so that FDA continues to receive critical safety information in a timely manner. For example, table 1 of the guidance outlines how companies should prioritize their submission of postmarketing safety reports during an influenza pandemic if normal processes of mandatory adverse event reporting are not feasible because of high employee absenteeism: Reports for pandemic influenza vaccines, drugs and biological products labeled for the treatment of influenza, drugs and biologics approved for less than three years, and products with special concerns as specified by FDA. The list includes reporting on newly approved products as the comment recommended. The guidance provides resources for companies establishing a COOP plan, but specifying the content of the COOP plans as suggested by the comment is beyond the scope of the guidance. Instead, the guidance provides the more general recommendation that ''each firm's pandemic influenza COOP plan should include instructions for reporting adverse events and the submission of any stored reports not submitted in the regulatory timeframes'' (see section III.B, page 2).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Add adverse event reporting plan to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
Total					258,000

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

Dated: December 30, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30907 Filed 1–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–P–0980]

Determination That REYATAZ (Atazanavir Sulfate) Capsules, 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that REYATAZ (atazanavir sulfate) capsules, 100 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for atazanavir sulfate, 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Na'Im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 240–402–3990.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

REYATAZ (atazanavir sulfate) capsules, 100 mg, is the subject of NDA 21–567, held by Bristol-Myers Squibb, and initially approved on June 20, 2003.

REYATAZ is a protease inhibitor indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV–1) infection in patients 3 months and older weighing at least 10 kilograms.

In a letter dated August 19, 2014, Bristol-Myers Squibb notified FDA that REYATAZ (atazanavir sulfate) capsules, 100 mg, had been discontinued. The REYATAZ 150-, 200-, and 300-mg capsule strengths continue to be marketed by Bristol-Myers Squibb. The 100-mg dosage strength of this drug product is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated July 7, 2014 (Docket No. FDA–2014–P–0980), under 21 CFR 10.30, requesting that the Agency determine whether REYATAZ (atazanavir sulfate) capsules, 100 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REYATAZ (atazanavir sulfate) capsules, 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REYATAZ (atazanavir sulfate) capsules, 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REYATAZ (atazanavir sulfate) capsules, 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REYATAZ (atazanavir sulfate) capsules, 100 mg, 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 REYATAZ (atazanavir sulfate) capsules, 100 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 30, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30909 Filed 1–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Her2 Monoclonal Antibodies, Antibody Drug Conjugates, and Site Specific Antibody Conjugate Methods for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to HUIYU Pharmaceuticals Co, Ltd located in Neijiang City, CHINA to practice the inventions embodied in U.S. Provisional Patent Application 61/833,732, filed June 11, 2013 entitled ''Her2-Specific Monoclonal Antibodies and Conjugates Thereof'' [HHS Ref. No.: E–351–2013/0–US–01], and International Application PCT/US2014/041492, filed June 9, 2014 entitled ''Her2-Specific Monoclonal Antibodies and Conjugates Thereof'' [HHS Ref. No.: E–351–2013/0–PCT–02], any PCT, US or foreign applications claiming the benefit of. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be limited to China, and the field of use may be limited to:

The use of the m860 monoclonal antibodies as mono-specific antibodies; or targeting moieties for immunoconjugates, wherein the antibodies are conjugated to auristatin F and analogues thereof, for the treatment of HER2 positive cancers.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before February 5, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell, Ph.D. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5282; Facsimile: (301) 435–4013; Email: *Eggerton.Campbell@nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern Antibody Drug Conjugates (ADCs). ADCs can demonstrate high efficacy as cancer therapeutics, however, much more can be done to improve their efficacy and safety profile. Site-specific antibody drug conjugation is a promising way to do this.

The scientists at the NIH have identified a fully human monoclonal antibody, m860, that binds to cell surface-associated Her2 with affinity comparable to that of Trastuzumab (Herceptin) but to a different epitope. In addition, the scientist developed a site-specific glycan engineering method to conjugate the antibody to the small molecule drug auristatin F. The ADC prepared though this site-specific approach shows very good stability, cell surface binding activity and also potent specific cell killing activity against Her2 positive cancer cells, including Trastuzumab resistant breast cancer cells. This ADC has the potential to be developed as a targeted therapeutic for Her2-overexpressing cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 30, 2014.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–30878 Filed 1–5–15; 8:45 am]

BILLING CODE 4140–01–P