

The numbers of patents submitted to FDA for listing in the Orange Book in 2012, 2013, and 2014 were 458, 509, and 617, respectively, for an annual average of 528 (458 patents + 509 patents + 617 patents)/3 years = 528 patents/year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our previous review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 74 (528 patents × 14 percent) patents will be multiple listings, and there will be a total of 602 patents (528 patents + 74 patents = 602 patents) declared on Form FDA 3542. We approved 86, 94, and 107 NDAs in calendar years 2012, 2013, and 2014, respectively, of which we estimate based on our previous review that approximately 71 percent submitted patent information for listing in the Orange Book. The remaining NDAs submitted Form FDA 3542 as required and declared that there were no relevant patents. We also approved approximately 101, 101, and 110 NDA supplements in FYs 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 200 instances (based on an average of 96 NDA approvals and 104 supplement approvals per year) where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 3.4 declarations (602 patent declarations + 74 no relevant patent declarations)/200 instances = 3.4 declarations per instance) on Form FDA 3542. We filed 112, 116, and 113 NDAs in 2012, 2013, and 2014, respectively, and 112, 112, 156 NDA supplements in 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 241 instances (based on an average of 114 NDAs filed and 127 NDA supplements filed per year) where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 819 declarations (241 instances × 3.4 declarations per instance = 819 declarations) on Form FDA 3542a submitted with these applications. Based upon information provided by regulated entities and other information, we previously estimated that the

information collection burden associated with § 314.50(h) (citing § 314.53) and Forms FDA 3542 and 3542a will be approximately 5 hours and 20 hours per response, respectively.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0129]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Licensing Provisions; Section 351(k) Biosimilar Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “General Licensing Provisions; Section 351(k) Biosimilar Applications” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On July 8, 2015, the Agency submitted a proposed collection of information entitled “General Licensing Provisions; Section 351(k) Biosimilar Applications” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0719. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

The Arthritis Foundation—Food and Drug Administration Accelerating Osteoarthritis Clinical Trials Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: Osteoarthritis is the most common form of arthritis, and occurs when the cartilage that cushions the bones of the joint break down and the bones begin to rub together. This can cause pain, swelling, and loss of motion of the joint. The Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research, in co-sponsorship with the Arthritis Foundation is announcing a workshop entitled, “Accelerating OA Clinical Trials Workshop”. The purpose of the workshop is to discuss recommendations from the international Arthritis Foundation Accelerating Osteoarthritis Clinical Trial workgroup and identify next steps in forging new approaches to osteoarthritis clinical trials that may improve the likelihood of successful conduct and outcomes of these trials and lead to the development of safe and effective treatments for osteoarthritis.

DATES: The workshop will be held on February 24, 2016, from 8 a.m. to 5:30 p.m., and February 25, 2016, from 8 a.m. to 2 p.m.

ADDRESSES: The workshop will be held at the Atlanta Airport Hilton, 1031 Virginia Ave., Atlanta, GA 30354.

FOR FURTHER INFORMATION CONTACT: Sarah Yim, Office of New Drugs, Center for Drug Evaluation and Research, email: *sarah.yim@fda.hhs.gov*; Amanda Niskar, Arthritis Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404-964-7545, FAX: 404-965-7807, email: *aniskar@arthritis.org*; or Becky Bosworth, Arthritis Foundation, Inc., 1330 West Peachtree St., Atlanta, GA 30309, 404-965-7673, email: *bbosworth@arthritis.org*.

SUPPLEMENTARY INFORMATION:

I. Background

The osteoarthritis (OA) community of clinicians, physicians and scientists have been challenged to get new treatments to market so that people with OA can benefit at the point of care. The Arthritis Foundation and FDA are convening experts to discuss alternative approaches to clinical trials in OA.