

is requested for the court to have jurisdiction over the appeal (405.1136(a)).

**B. Medicare Part C (Medicare Advantage) Appeals**

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Medicare Part C (MA) appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C (MA) appeals are found at 42 CFR part 422, Subpart M. Specifically, 422.600 and 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party to the reconsideration, except the MA organization, who is dissatisfied with the reconsideration determination, a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states, in part, that any party, including the MA organization, may request judicial review if, the AIC meets the threshold requirement established annually by the Secretary.

**C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans**

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR part 422, Subpart M, and as discussed previously, apply to these appeals. The Medicare Part C appeals rules also apply to health care prepayment plan appeals.

**D. Medicare Part D (Prescription Drug Plan) Appeals**

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 101 of the MMA added section 1860D-4(h)(1) of the Act regarding Part D appeals. This statutory provision requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. As noted previously, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR part 423, Subparts M and U. The regulations at §423.562(c) prescribe that, unless the Part D appeals rules provide otherwise, the Part C appeals rules (including the annually adjusted AIC threshold amount) apply to Part D appeals to the extent they are appropriate. More specifically, 423.1970 and 423.1976 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.1970(a) grants a Part D enrollee, who is dissatisfied with the independent review entity (IRE) reconsideration determination, a right to an ALJ hearing if the amount remaining in controversy after the IRE reconsideration meets the threshold amount established annually by the Secretary. Section 423.1976(a) and (b) allow a Part D enrollee to request judicial review of an ALJ or MAC decision if, in part, the AIC meets the threshold amount established annually by the Secretary.

**II. Annual AIC Adjustments**

**A. AIC Adjustment Formula and AIC Adjustments**

As previously noted, section 940 of the MMA requires that the AIC threshold amounts be adjusted annually, beginning in January 2005, by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of \$10.

**B. Calendar Year 2012**

The AIC threshold amount for ALJ hearing requests will remain at \$130 and the AIC threshold amount for judicial review will rise to \$1,350 for CY 2012. These updated amounts are based on the 34.51 percent increase in the medical care component of the CPI from July 2003 to July 2011. The CPI level was at 297.600 in July 2003 and rose to 400.305 in July 2011. This change accounted for the 34.51 percent increase. The AIC threshold amount for ALJ hearing requests changes to \$134.51 based on the 34.51 percent increase. In accordance with section 940 of the MMA, this amount is rounded to the nearest multiple of \$10. Therefore, the 2012 AIC threshold amount for ALJ hearings is \$130. The AIC threshold amount for judicial review changes to \$1,345.11 based on the 34.51 percent increase. This amount was rounded to the nearest multiple of \$10, resulting in the 2012 AIC threshold amount of \$1,350 for judicial review.

**C. Summary Table of Adjustments in the AIC Threshold Amounts**

In the following table we list the CYs 2005 through 2012 threshold amounts.

	CY 2005	CY 2006	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
ALJ Hearing .....	\$100	\$110	\$110	\$120	\$120	\$130	\$130	\$130
Judicial Review .....	1,050	1,090	1,130	1,180	1,220	1,260	1,300	1,350

**III. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774,

Medicare—Supplementary Medical Insurance Program)

Dated: September 8, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0481]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Investigational Uses**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 24, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0117. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, *juanmanuel.vilela@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

**New Animal Drugs for Investigational Uses—21 CFR Part 511 (OMB Control Number 0910-0117)—Extension**

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. Section 512(j) of the FD&C Act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and

address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse. The agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are the persons who use new animal drugs for purposes of an investigation.

In the **Federal Register** of June 28, 2011 (76 FR 37814), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4) .....	206	6.01	1,238	1	1,238
511.1(b)(5) .....	206	.34	70	8	560
511.1(b)(6) .....	206	.01	2	1	2
511.1(b)(8)(ii) .....	206	.07	15	2	30
511.1(b)(9) .....	206	.07	15	8	120
Total .....					1,950

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3) .....	206	2.30	473	1	473
511.1(b)(3) .....	206	6.01	1,238	1	1,238
511.1(b)(7)(ii) .....	206	6.01	1,238	3.5	4,333
511.1(b)(8)(i) .....	206	6.01	1,238	3.5	4,333
Total Burden Hours .....					10,377

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record

preparation, and maintenance for this collection of information is based on

agency communication with industry. Based on the number of sponsors

subject to animal drug user fees, FDA estimates that there are 206 respondents. We use this estimate consistently throughout the table and calculate the “annual frequency per respondent” by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.*, the number of respondents, the number of record keepers, the number of NCIEs received, *etc.*) is derived from agency records.

Dated: September 19, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0651]

**Determination That LOXITANE (Loxapine Succinate) Capsules and Three Other Drug Products 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) has determined that the four drug products listed in this document were not withdrawn from

sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:**

Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993-0002, 301-796-3601.

**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 approved 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 generally known as the “Orange Book.” Under FDA regulations, a drug is withdrawn 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 017525 .....	LOXITANE (loxapine succinate) Capsules, Equivalent to (EQ) 5 milligram (mg) base, EQ 10 mg base, EQ 25 mg base, and EQ 50 mg base.	Watson Laboratories Inc., 417 Wakara Way, Suite 100, Salt Lake City, UT 84108.
NDA 017525 .....	LOXITANE (loxapine succinate) Tablets, EQ 10 mg base, EQ 25 mg base, and EQ 50 mg base.	Do.
NDA 020403 .....	ZOFRAN AND DEXTROSE IN PLASTIC CONTAINER (ondansetron hydrochloride) Injection, EQ 0.64 mg/ milliliter.	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709-3398.
NDA 020828 .....	FORTOVASE (saquinavir) Capsule, 200 mg .....	Hoffmann La Roche Inc., 340 Kingsland St., Nutley, NJ 07110.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued

from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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.

Dated: September 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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