20050377	Bain Capital Fund VII-E, L.P.	Samsonite Corporation	Samsonite Corporation

TRANSACTIONS GRANTED EARLY TERMINATION - 12/29/2004

TRANS #	ACQUIRING	ACQUIRED	ENTITIES
20050353	Mitsubishi Tokyo Finaicial Group, Inc.	UFJ Holdings, Inc.	UFJ Holdings, Inc.
20050354	International Steel Group, Inc.	DTE Energy Company	DTE Energy Services, Inc.
20050360	Eagle Materials Inc.	R.A. Cement Investors	Illinois Cement Company
20050381	ALH Holding Inc.	Bain Capital Fund V, L.P.	Alliance Laundry Holdings LLC

TRANSACTIONS GRANTED EARLY TERMINATION - 12/30/2004

TRANS #	ACQUIRING	ACQUIRED	ENTITIES
20050337	Smiths Group plc	JPMorgan Chase & Co.	MedVest Holdings Corp.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative or Renee Hallman, Case Management Assistant, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 05–594 Filed 1–11–04; 8:45 am]

BILLING CODE 6750–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0003]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on regulations requiring the distribution of patient labeling, called Medication Guides, for certain products that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information.

DATES: Submit written or electronic comments on the collection of information by March 14, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501–3520), 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, including each proposed extension of an existing 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.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control Number 0910–0393)—Extension

FDA regulations require the distribution of Medication Guides for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug

reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA, and the estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

21 CFR 208.26 (a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

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
208.20	35	1.34	47	242	11,374
314.70(b)(3)(ii) 601.12(f)	3	1	3	24	72
208.24(e)	55,000	20	1,100,000	.0014	1540
208.26(a)	1	1	1	4	4
Total					12,990

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

Dated: January 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–659 Filed 1–11–05; 3:26 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Services; Submission for OMB Review; Comment Request

Request for generic clearance to collect public comments on the proposed standards of care for chimpanzees in the federally supported chimpanzee sanctuary system.

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Research Services, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995 unless it displays a currently valid OMB control number.

Proposed Collection: Title: Request for Generic Clearance to collect public comments on the Proposed Standards of Care Regulations covering chimpanzees in the federally supported Chimpanzee Sanctuary System. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Chimpanzee Health Improvement, Maintenance, and Protection Act of 2000 (Public Law 106–551) requires the Secretary of the Department of Health and Human Services to develop Standards of Care Regulations for chimpanzees in the Sanctuary System. The Act further requires the Secretary to publish the proposed standards in the **Federal Register** to provide a 60 day period for public comment on the proposed standards. Following receipt of public comments, NCRR/NIH will consider these comments in preparing the final regulations for the sanctuary system. The public includes members of the general population, interested communities (local, regional, and national organizations), and non-profit business entities. Input from the public will allow the NCRR/NIH staff to receive critical review of the standards from different stakeholders, provide a review and analyses of the burden estimated by the government, and help assure that the proposed standards are necessary and current. *Frequency of Response:* One time event. *Affected Public:* Non-profit entities serving as a contractor to the government to operate and maintain the federally supported Chimpanzee Sanctuary System. *Type of Respondents:* Non-profit businesses that possess qualified staff and resources needed to develop, operate, and maintain several hundred chimpanzees. *Estimated number of respondents:* 1–3. *Number Respondents per Response:* 1–3. *Average Burden Hours Per Response:* 15.4. *Burden Hours Requested:* 186.95. Total annualized cost to respondents is estimated at $8412.75. There is no capital, operating, and/or maintenance costs to report.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents*	Annual frequency	Average burden hours	Annual burden hours per response
Reporting:				
§ 9.3(a)(7)(v)(C)	1–3	2	6	12
§ 9.6(c)(6)	1–3	3	2	6