

## TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 012098 AND 013098—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
NCO Group, Inc., TeleSpectrum Worldwide Inc., TeleSpectrum Worldwide Inc .....	98-1456	01/30/98
Golder, Thomas, Cressey, Rauner Fund V, L.P., The Modern Group, Inc., The Modern Group, Inc. (Dragon Rental Division) .....	98-1457	01/30/98
Clayton, Dubilier & Rice Fund V Limited Partnership, Norfolk Southern Corporation, North American Van Lines, Inc. Enron Corp., Compagnie Generale des Eaux (a French corporation), Anjou Construction and Services Company; Limbach Holdin .....	98-1460	01/30/98
Federal-Mogul Corporation, Fel-Pro Realty Corporation, Fel-Pro Realty Corporation .....	98-1462	01/30/98
The Robert Rosenkranz Trust, Dennis N. Horowitz, Smith St. John Company, Smith St. John of Georgia, Inc., .....	98-1467	01/30/98
H&R Block, Inc., Estate of David B. Clayton, Estate of David B. Clayton .....	98-1470	01/30/98
Dominion Resources, Inc., Unicom Corporation, Commonwealth Edison Company .....	98-1471	01/30/98
Cablevision Systems Corporation, The Wiz, Inc. (Debtor-in-Possession), The Wiz, Inc. (Debtor-in-Possession) .....	98-1484	01/30/98
	98-1513	01/30/98

**FOR FURTHER INFORMATION CONTACT:**

Sandra M. Peay or Parcellena P.

Fielding, Contact Representatives  
Federal Trade Commission, Premerger  
Notification Office, Bureau of  
Competition, Room 303, Washington,  
D.C. 20580, (202) 326-3100.

By Direction of the Commission.

**Donald S. Clark,**

Secretary.

[FR Doc. 98-3505 Filed 2-11-98; 8:45 am]

BILLING CODE 6750-01-M

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES****Food and Drug Administration**

[Docket No. 97N-0327]

**Agency Information Collection  
Activities; Submission for OMB  
Review; Comment Request**AGENCY: Food and Drug Administration,  
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug  
Administration (FDA) is announcing

that the proposed collection of  
information listed below has been  
submitted to the Office of Management  
and Budget (OMB) for review and  
clearance under the Paperwork  
Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the  
collection of information by March 16,  
1998.

**ADDRESSES:** Submit written comments  
on the collection of information to the  
Office of Information and Regulatory  
Affairs, OMB, New Executive Office  
Bldg., 725 17th St. NW., rm. 10235,  
Washington, DC 20503, Attn: Desk  
Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:**  
JonnaLynn P. Capezzuto, Office of  
Information Resources Management  
(HFA-250), Food and Drug  
Administration, 5600 Fishers Lane,  
Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In  
compliance with section 3507 of the  
PRA (44 U.S.C. 3507), FDA has  
submitted the following proposed  
collection of information to OMB for  
review and clearance.

**Petition For Administrative Stay of  
Action—21 CFR 10.35—(OMB Control  
Number 0910-0194)—Reinstatement**

FDA regulations in 21 CFR 10.35,  
issued under the authority of section  
701(a) of the Federal Food, Drug, and  
Cosmetic Act (21 U.S.C. 371(a)), set  
forth the format and procedures by  
which an interested person may file a  
petition for an administrative stay of  
action.

Respondents to this collection of  
information are interested persons who  
choose to file a petition for an  
administrative stay of action. Such a  
petition must: (1) Identify the decision  
involved; (2) state the action requested,  
including the length of time for which  
a stay is requested; and (3) include a  
statement of the factual and legal  
grounds on which the interested person  
relies in seeking the stay. The  
information provided in the petition is  
used by the agency to determine  
whether the requested stay should be  
granted.

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

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.35	7	1	7	100	700

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

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that seven such petitions are received by the agency annually, with each requiring approximately 100 hours of preparation time.

Dated: February 4, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-3504 Filed 2-11-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0049]

#### Draft Guidance for Industry on Environmental Assessment of Human Drug and Biologics Applications; 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 "Environmental Assessment of Human Drug and Biologics Applications." This draft guidance is intended to provide information on when an environmental assessment (EA) should be submitted in support of a human drug or biologics application and recommendations on how to prepare EA's.

**DATES:** Written comments may be submitted on the draft guidance document by April 13, 1998. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send two self-addressed labels to assist that office in processing your request. Submit

written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. See the **Supplementary Information** section for electronic access to this document.

#### FOR FURTHER INFORMATION CONTACT:

Nancy B. Sager, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5629 or Daniel C. Kearns, Center for Biologics Evaluation and Research (HFM-206), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3031.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental effects of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental effect of approving drug and biologics applications as an integral part of its regulatory process. Under the President's reinventing Government initiatives announced in April 1995, FDA reevaluated and revised its environmental regulations to reduce the number of EA's required to be submitted by industry and, consequently, the number of findings of no significant impact prepared by the agency under NEPA.

In the **Federal Register** of April 3, 1996 (61 FR 14922) (republished May 1, 1996 (61 FR 19476)), FDA issued for public comment a notice of proposed rulemaking that proposed additional categorical exclusions for those actions the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have determined normally do not individually or cumulatively have a significant effect on the quality of the human environment. The final rule was published in the **Federal Register** of July 29, 1997 (62 FR 40570), and became

effective on August 28, 1997. This draft guidance is based on the final rule and is consistent with the Food and Drug Administration Modernization Act of 1997; it is intended to supersede CDER's "Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements," which published in November 1995.

FDA's regulations in part 25 (21 CFR part 25) specify that environmental assessments must be submitted as part of certain new drug applications, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, investigational new drug applications, and for various other actions (see § 25.20), unless the action qualifies for a categorical exclusion.

This guidance provides information on when an EA should be submitted and recommendations on how to prepare EA's for submission to CDER and CBER for these drug or biologics applications. Topics covered include: (1) When categorical exclusions apply, (2) when to submit an EA, (3) the content and format of EA's, (4) specific guidance for the environmental issues that are most likely to be associated with human drugs and biologics, (5) test methods, (6) an applicant's treatment of confidential information submitted in support of an EA, and (7) drug master files and master files.

This draft guidance represents the agency's current thinking on the environmental assessment of human drug and biologics applications. 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 requirement of the applicable statute, regulations, or both.

##### II. Request for Comments

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

##### III. Electronic Access

An electronic version of this draft guidance is available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/cberftp.html>.