TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 012098 AND 013098—Continued

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

FOR FURTHER INFORMATION CONTACT:
Sandra M. Peay or Parcellena P. Fielding, Contact Representatives

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).

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>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
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<tbody>
<tr>
<td>10.35</td>
<td>7</td>
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</tr>
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</table>

1 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.


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–206), 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 (CDER), 8100 Greensboro Dr., Suite 3750, McLean, VA 22102, fax: (703) 746–1559, phone: (703) 746–1965, or e-mail: nbsager@cder.fda.gov. Nancy B. Sager, Center for Biologics Evaluation and Research (CBER), 8201 Grosvenor Lane, Rockville, MD 20852, fax: (301) 443–5100, phone: (301) 443–6656, or e-mail: nb.sager@fda.cber.hhs.gov. Nancy B. Sager, Center for Biologics Evaluation and Research (CBER), 8201 Grosvenor Lane, Rockville, MD 20852, fax: (301) 443–5100, phone: (301) 443–6656, or e-mail: nb.sager@fda.cber.hhs.gov.

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) (repubicated 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 requirements 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.