

**FOR FURTHER INFORMATION CONTACT:** Howard Morse or William Baer, FTC/H-394, Washington, D.C. 20580. (202) 326-2949 or 326-2932.

**SUPPLEMENTARY INFORMATION:** On Friday, January 3, 1997, there was published in the **Federal Register**, 62 FR 409, a proposed consent agreement with analysis In the Matter of Ciba-Geigy Limited, et al., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to divest, as set forth in the proposed consent agreement, indisposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

**Benjamin I. Berman,**  
*Acting Secretary.*

[FR Doc. 97-32635 Filed 12-12-97; 8:45 am]

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## FEDERAL TRADE COMMISSION

[Dkt. C-3727]

### Jeanette L. Douglas Co.; Prohibited Trade Practices, and Affirmative Corrective Actions

**AGENCY:** Federal Trade Commission.

**ACTION:** Consent Order.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order prohibits, among other things, Jeanette L. Douglas, an officer of Computer Business Services, Inc. ("CBSI"), from misrepresenting the earnings or success rate of CBSI investors; the existence of a market for CBSI's products or services; the amount of time it takes investors to recoup their investments; and from making any representation regarding the performance, benefits, efficacy or success rate of any product or service unless she possesses reliable evidence to substantiate the claims. The consent order also prohibits the use of misleading testimonials or endorsements and requires certain disclosures to investors.

**DATES:** Complaint and Order issued March 24, 1997.<sup>1</sup>

**FOR FURTHER INFORMATION CONTACT:** C. Steven Baker or Catherine Fuller, Federal Trade Commission, Chicago Regional Office, 55 East Monroe St., Suite 1860, Chicago, IL 60603. (312) 353-8156 or (312) 353-5576.

**SUPPLEMENTARY INFORMATION:** On Friday, January 17, 1997, there was published in the **Federal Register**, 62 FR 2671, a proposed consent agreement with analysis In the Matter of Jeanette L. Douglas Co., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

**Benjamin I. Berman,**  
*Acting Secretary.*

[FR Doc. 97-32637 Filed 12-12-97; 8:45 am]

BILLING CODE 6750-01-M

## FEDERAL TRADE COMMISSION

[Dkt. C-3728]

### Phillips Petroleum Company; Prohibited Trade Practices, and Affirmative Corrective Actions

**AGENCY:** Federal Trade Commission.

**ACTION:** Consent order.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order requires, among other things, the Oklahoma-based corporation to divest approximately 160 miles of pipeline belonging to ANR Pipeline Company and Phillips in the Anadarko Basin area, and to maintain the assets in their current condition and to provide customers under the contract with ANR with gathering services at existing terms and conditions pending divestiture. The consent order also requires Phillips, for ten years, to notify the Commission before acquiring during any 18-month period more than five miles of gas

gathering pipelines in the specified areas of the Oklahoma counties.

**DATES:** Complaint and Order issued March 28, 1997.<sup>1</sup>

**FOR FURTHER INFORMATION CONTACT:** George Cary, FTC/H-374, Washington, DC 20580. (202) 326-3741.

**SUPPLEMENTARY INFORMATION:** On Friday, January 10, 1997, there was published in the **Federal Register**, 62 FR 1459, a proposed consent agreement with analysis In the Matter of Phillips Petroleum Company, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments have been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to divest, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

**Benjamin I. Berman,**  
*Acting Secretary.*

[FR Doc. 97-32638 Filed 12-12-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Agency for Toxic Substances and Disease Registry; Senior Executive Service; Performance Review Board Members

**AGENCY:** Centers for Disease Control and Prevention (CDC), and Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Title 5, U.S. Code, Section 4314(c)(4) of the Civil Service Reform Act of 1978, Pub. L. 95-454, requires that appointment of Performance Review Board members be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Connie Clayton, Human Resources Management Office, Office of Program Support, Centers for Disease Control and Prevention, 4770 Buford Highway,

<sup>1</sup> Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H-130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

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Mailstop K-07, Atlanta, Georgia 30341-3724, telephone 770-488-1874.

**SUPPLEMENTARY INFORMATION:** The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services in the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry:

Claire V. Broome, M.D., Chairperson  
Helene D. Gayle, M.D., M.P.H.  
James M. Hughes, M.D.  
Arthur C. Jackson  
Richard J. Jackson, M.D., M.P.H.  
Wanda K. Jones, Dr.P.H.  
James S. Marks, M.D., M.P.H.  
Peter J. McCumiskey  
Linda Rosenstock, M.D., M.P.H.

Dated: December 8, 1997.

**Claire Broome,**

*Deputy Director, Centers for Disease Control and Prevention (CDC) and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).*

[FR Doc. 97-32589 Filed 12-12-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Oversight Committee and Request for Submissions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the 1998 meetings of its clinical hold oversight committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. For each meeting, FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

**DATES:** The next meetings will be held on February 10, 1998; May 12, 1998; August 11, 1998; and November 10, 1998. Biological product companies may submit review requests for the February meeting by January 12, 1998;

for the May meeting by March 31, 1998; for the August meeting by June 30, 1998; and for the November meeting by September 29, 1998.

**ADDRESSES:** Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF-7), 5600 Fishers Lane, rm. 14-105, Rockville, MD 20857, 301-827-3390.

**FOR FURTHER INFORMATION CONTACT:** Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

**SUPPLEMENTARY INFORMATION:** FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly

with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting an oversight committee to review clinical holds (see 61 FR 1031 at 1033, January 11, 1996). CBER held its first clinical hold oversight committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered "anonymously." The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and