

§ 76.673 Appointment and functions of a hearing officer.

(a) If a grantee or subgrantee requests a hearing to show cause why the Secretary should not implement a bypass, the Secretary appoints a hearing officer and notifies appropriate representatives of the affected private school children that they may participate in the hearing.

(b) The hearing officer has no authority to require or conduct discovery or to rule on the validity of any statute or regulation.

(c) The hearing officer notifies the grantee, subgrantee, and representatives of the private school children of the time and place of the hearing.

(Authority: 20 U.S.C. 2727(b)(4)(A), 2972(h)(1), 2990(c), 3223(c))

§ 76.674 Hearing procedures.

(a) The following procedures apply to a show cause hearing regarding implementation of a bypass:

(1) The hearing officer arranges for a transcript to be taken.

(2) The grantee, subgrantee, and representatives of the private school children each may—

(i) Be represented by legal counsel; and

(ii) Submit oral or written evidence and arguments at the hearing.

(b) Within 10 days after the hearing, the hearing officer—

(1) Indicates that a decision will be issued on the basis of the existing record; or

(2) Requests further information from the grantee, subgrantee, representatives of the private school children, or Department officials.

(Authority: 20 U.S.C. 2727(b)(4)(A), 2972(h)(1), 2990(c), 3223(c))

§ 76.675 Posthearing procedures.

(a)(1) Within 120 days after the record of a show cause hearing is closed, the hearing officer issues a written decision on whether a bypass should be implemented.

(2) The hearing officer sends copies of the decision to the grantee, subgrantee, representatives of the private school children, and the Secretary.

(b) Within 30 days after receiving the hearing officer's decision, the grantee, subgrantee, and representatives of the private school children may each submit to the Secretary written comments on the decision.

(c) The Secretary may adopt, reverse, modify, or remand the hearing officer's decision.

(Authority: 20 U.S.C. 2727(b)(4)(A), 2972(h)(1), 2990(c), 3223(c))

§ 76.676 Judicial review of a bypass action.

If a grantee or subgrantee is dissatisfied with the Secretary's final action after a proceeding under §§ 76.672 through 76.675, it may, within 60 days after receiving notice of that action, file a petition for review with the United States Court of Appeals for the circuit in which the State is located.

(Authority: 20 U.S.C. 2727(b)(4)(B)-(D), 2972(h)(2)-(4), 2990(c), 3223(c))

§ 76.677 Continuation of a bypass.

The Secretary continues a bypass until the Secretary determines that the grantee or subgrantee will meet the requirements for providing services to private school children.

(Authority: 20 U.S.C. 2727(b)(3)(D), 2972(f), 1221e-3(a)(1)) 7. A new § 76.910 is added to read as follows:

§ 76.910 Cooperation with audits.

A grantee or subgrantee shall cooperate with the Secretary and the Comptroller General of the United States or any of their authorized representatives in the conduct of audits authorized by Federal law. This cooperation includes access without unreasonable restrictions to records and personnel of the grantee or subgrantee for the purpose of obtaining relevant information.

(Authority: 5 U.S.C. App. 4(a)(1); 20 U.S.C. 1221e-3(a)(1), 1232f)

PART 78—EDUCATION APPEAL BOARD

8. The authority citation for Part 78 is revised to read as follows:

Authority: 20 U.S.C. 1234-1234c (Supp. IV 1986), unless otherwise noted.

§ 78.2 [Amended]

9. Section 78.2 is amended by removing the paragraph designation for paragraph (a), removing paragraph (b), and redesignating paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(4)(i), (a)(4)(ii), (a)(4)(iii), and (a)(5) as paragraphs (a), (b), (c), (d), (d)(1), (d)(2), (d)(3), and (e), respectively.

§ 78.3 [Amended]

10. Section 78.3 is amended by removing “§ 78.2(a)(4)” in paragraph (c) of the definition of “Appellant” and adding, in its place, “§ 78.2(d)”, and by removing “§ 78.2(a)(4)” in paragraph (b)(2) of the definition of “Party” and adding, in its place, “§ 78.2(d)”.

§ 78.6 [Amended]

11. Section 78.6 is amended by removing the paragraph designation for paragraph (a), removing paragraph (b), and redesignating paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7), as paragraphs (a), (b), (c), (d), (e), (f), and (g), respectively.

§ 78.21 [Amended]

12. Section 78.21 is amended by removing “(a)(4) through (a)(6)” in paragraph (a)(2) and adding, in its place, “(d) through (f)”.

§ 78.22 [Amended]

13. Section 78.22 is amended by removing “(a)(4) through (a)(6)” in paragraph (a) and adding, in its place, “(d) through (f)”.

§ 78.42 [Amended]

14. Section 78.42 is amended by removing paragraph (c).

PART 204—[REMOVED]

15. Part 204 is removed.

[FR Doc. 88-24236 Filed 10-20-88; 8:45 am]

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Federal Register

Friday
October 21, 1988

Part IV

Department of Labor

Employment Standards Administration,
Wage and Hour Division

29 CFR Part 801

Application of the Employee Polygraph
Protection Act of 1988; Final Rule

DEPARTMENT OF LABOR

Employment Standards
Administration, Wage and Hour
Division

29 CFR Part 801

Application of the Employee
Polygraph Protection Act of 1988

AGENCY: Wage and Hour Division, ESA, Labor.

ACTION: Interim final rule; request for comments.

SUMMARY: This document provides interim final regulations for the implementation of the Employee Polygraph Protection Act of 1988, which was signed into law June 27, 1988, and is effective December 27, 1988.

The purpose of the regulations is to provide protection for most private-sector employees from lie detector testing, either pre-employment or during the course of employment, with certain limited exceptions.

DATES: *Effective Date:* The interim final rule is effective December 27, 1988. Any covered employer, not otherwise exempt, who wishes to use a lie detector test after that date will be subject to this interim final rule.

Comments: Comments are due on or before February 27, 1989.

ADDRESSES: Submit written comments (preferably in triplicate) to Paula V. Smith, Administrator, Wage and Hour Division, U.S. Department of Labor, Room S-3502, 200 Constitution Avenue NW., Washington, DC 20210. Commenters who wish to receive notification of receipt of comments are requested to include a self-addressed stamped post card.

FOR FURTHER INFORMATION CONTACT: Paula V. Smith, Administrator, Wage and Hour Division, U.S. Department of Labor, Room S-3502, 200 Constitution Avenue NW., Washington, DC 20210, (202) 523-8305. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:**I. Background**

On June 27, 1988, the Employee Polygraph Protection Act of 1988 (EPPA or the Act) was enacted into law. EPPA prohibits most private employers (Federal, State and local government employers are exempted from the Act) from using any lie detector tests either for pre-employment screening or during the course of employment. In addition, testing by the Federal Government of experts, consultants, or employees of Federal contractors engaged in national security intelligence or

counterintelligence functions is permitted. The law contains several limited exemptions which authorize polygraph tests under certain conditions, including: (1) The testing of employees who are reasonably suspected of involvement in a workplace incident that results in economic loss or injury to the employer's business; (2) the testing of some prospective employees of private armored car, security alarm, and security guard firms; and (3) the testing of some current and prospective employees in firms authorized to manufacture, distribute, or dispense controlled substances. Employers who violate any of the Act's provisions may be assessed civil money penalties up to \$10,000.

While the law provides for an effective date six months from the date of enactment, it also provides that the Secretary of Labor issue appropriate regulations "not later than 90 days after the date of enactment." Given the constraints of time and the statutory mandate to issue final regulations within 90 days of enactment, the Department of Labor is publishing this final rule on an interim basis, simultaneously inviting comments from interested parties. After review of the comments, the Department will either issue a proposal or a final regulation, based on the comments received.

II. Paperwork Reduction Act

Recordkeeping requirements contained in the regulation (§ 801.30) are being submitted to the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) for review.

Public reporting burden for this collection of information is estimated to average as follows: 1. (A) Written Notice to Examinee of Polygraph Testing—5 minutes per response; (B) Additional Information in Notice to Examinee of Polygraph Testing for Ongoing Investigations—½ hour per response; 2. Written Notice to Polygraph Examiner Identifying Persons to be Examined—5 minutes per response; 3. Written Notice of Test Results to Examinee Prior to Adverse Action—1 minute per response; 4. Record of number of tests conducted daily and length of each test—½ minute per response; 5. Maintenance of test record—1 minute per response; (see 29 CFR 801.30), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any

other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, U.S. Department of Labor, Room N-1301, 200 Constitution Avenue NW., Washington, DC 20210; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

III. Summary of Rule

The regulations in this Part are divided into six subparts. Subpart A contains the provisions generally applicable to covered employers, including the requirements relating to the prohibitions on lie detector use and the posting of notices. Subpart A also sets forth interpretations regarding the effect of section 10 of the Act on other laws or collective bargaining agreements. Subpart B sets forth rules regarding the statutory exemptions from application of the Act. Subpart C sets forth the restrictions on polygraph usage under such exemptions. Subpart D sets forth the recordkeeping requirements and the rules on disclosure of polygraph test information. Subpart E deals with the authority of the Secretary of Labor and the enforcement provisions under the Act. Subpart F contains the procedures and rules of practice necessary for the administrative enforcement of the Act.

The Department met informally with outside parties who provided background information with respect to the preparation of this rule. Included in such meetings were representatives of security service companies and related trade associations; representatives of retail trade associations; representatives of the polygraph industry; and representatives of trade associations involved with controlled substances. Meetings were also held with officials of the Drug Enforcement Administration and the Department of Defense.

In developing this rule, a number of issues have been identified and explored. The Department has tentatively resolved these issues as described below, and it particularly invites comments on the following issues:

(1) The legislative intent as to the scope of the security service industry exemption is not entirely clear on the treatment of employees hired to install alarms in or guard commercial or retail establishments and residences. We have tentatively concluded that the section 7(e)(1)(B) exemption does not apply to security guard or security alarm firms protecting private homes or businesses not primarily engaged in the handling,

trading, transferring, or storing of the assets enumerated in the statute. There is an argument, however, that the exemption should be interpreted more broadly, so as to include such employees. If the exemption were so interpreted, it appears that virtually all employees in this industry would be subject to pre-employment polygraph tests. Such an interpretation is not easily reconciled with the language of the statute itself, which identifies specific types of security work as included within the exemption. Comment is specifically invited on the scope of the exemption as provided in § 801.14.

(2) The Congress specifically directed the Department to develop regulations which would list the types of "facilities, materials, or operations" having a significant impact on the health or safety of any State or political subdivision or the national security. It is evident the legislative intent was to protect the safety and health of the general public. The Department has listed a number of such "facilities, materials, or operations" in § 801.14(i). Comments are specifically requested on the scope of this list.

(3) The rule broadly interprets the term "prospective employee" for purposes of the security service and controlled substance exemptions. In particular, current employees of the employer, who were initially hired to perform duties which do not fall within the scope of the exemptions (and who, therefore, are not subject to pre-employment polygraph tests), could be tested as "prospective employees" the first time (only) they are re-assigned or promoted to a position with duties that do fall within the scope of the exemptions. We have found no pertinent legislative history on this issue. We believe, however, that some latitude is necessary in the definition of "prospective employee" for purposes of the exemption, so that current employees of an employer will not be unfairly disadvantaged, with respect to non-employees, in competition for positions which may be subject to the exemption. We believe that this construction, contained in §§ 801.13(d) and 801.14(b), is reasonable, given the realities of the workplace.

(4) Except as noted above, the rule makes no allowances for pre-employment testing to be conducted after an applicant is initially hired by an employer. It has been suggested that there are situations in which it is not feasible or practical to conduct the test prior to the actual hiring date and that it would be consistent with the purposes of the Act to permit testing subsequent

to hiring in some circumstances. Comment is invited on the question whether it would be consistent with the Act to permit such testing. If so, under what circumstances, and what would be a reasonable period (e.g., one day, one week, one month) subsequent to hiring in which such testing should be permitted?

(5) The rule interprets the terms "direct access" and "access" differently for purposes of the controlled substance exemption (§ 801.13). This, "direct access", which is one of the elements necessary for pre-employment testing, is more narrowly defined than "access", an element required for testing of current employees during an ongoing investigation. In the latter case, however, the "access" must be to the specific person or property that is the subject of the investigation. The Department believes this interpretation is consistent with the statute and legislative history.

(6) The legislative history of the Act indicates Congress' intention that the controlled substance exemption not be applicable to truck drivers and that the exemption extend only to persons or entities registered with the Drug Enforcement Administration. The Controlled Substances Act exempts from registration requirements common or contract carriers and warehouses whose possession of a controlled substance is in the usual course of their business. Accordingly, § 801.13(b)(2) excludes employees of common or contract carriers or public warehouses from this exemption.

(7) Inventory shortages are common throughout many industries. Section 801.12 is intended to preclude the mere existence of an inventory shortage, in and of itself, from being a basis for testing of current employees since it does not meet the specific incident requirement of the exemption. Are the safeguards in the rule sufficient to prevent the random testing of employees, or classes of employees, on a routine or regular basis?

(8) The Act provides several examples of events which would constitute an economic loss or injury for purposes of the ongoing investigation exemption, including theft, embezzlement, and sabotage. Section 801.12 adds other examples, including check-kiting and money-laundering, which were contained in the legislative history. Comment is invited on the question whether there are other examples, or other classes of activity, which should be included in the scope of "economic loss" for purposes of this exemption.

(9) Section 801.14 defines the statutory term "primary business purpose" to mean the activity from which 50 percent or more of the employer's business income is derived. Thus, at least 50 percent of an employer's annual dollar volume of business must be derived from the types of security activities within the scope of the exemption in order for the exemption to apply. Would some alternative definition of "primary business purpose" better effectuate the statutory scheme, or be more workable?

(10) The Act requires that individuals must be given "reasonable written notice" of the date, time, location and other information about a polygraph test. Sections 801.12(g)(2) and 801(c)(1)(A) define "reasonable" as at least 48 hours prior to the examination. Should some other minimum time frame be used to define "reasonable", and if so, why?

Executive Order 12291

This rule is not classified as a "major rule" under Executive Order 12291 on Federal Regulations, because it is not likely to result in: (1) An annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign enterprises in domestic or export markets. Therefore no regulatory impact analysis is required.

The Department's determination that the regulation is not subject to a regulatory impact analysis is based on the following:

(a) The Congressional Budget Office estimated the cost for EPPA to be \$1 million to the Federal Government and that EPPA will have no impact on State and local governments.

(b) Further, the legislative history on EPPA shows a lack of any evidence that internal theft rates are higher in States which prohibit the use of polygraph tests. Also, there are no conclusive studies which show that polygraph testing reduces employee crime.

(c) Section 7 of EPPA permits certain employers to continue to conduct polygraph testing and permits all employers to request an employee to take a test, under certain conditions, when it is administered as part of an ongoing investigation. Consequently, any economic costs due to increased theft attributable to the absence of polygraph testing will be minimized.

(d) The net employment effect of EPPA will not be significant. As

employers turn to different hiring procedures and screening techniques, employment gains in the occupations associated with these alternative hiring procedures will offset any employment loss in the polygraph testing field.

Preliminary Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 requires agencies to prepare regulatory flexibility analyses, and to develop alternatives whenever possible, in drafting regulations that will have "a significant economic impact on a substantial number of small entities." The following analysis assesses the impact of these regulations on small entities required by the Act.

(1) Reasons Why Action by Agency Is Being Considered

On June 27, 1988 the Employee Polygraph Protection Act of 1988 was enacted into law. This Act, which is effective December 27, 1988, generally prevents employers engaged in interstate commerce from using any lie detector tests, with certain exemptions, either for pre-employment screening or during the course of employment. Section 5 of the Act requires the Secretary of Labor to promulgate such rules and regulations as may be necessary to carry out the Act. This interim final rule is being issued to implement the Act.

(2) Objectives of and Legal Basis for Rule

This interim final rule is issued pursuant to section 5 of the Employee Polygraph Protection Act of 1988. Its objective is to enable employers and polygraph examiners to comply with the requirements of the Act, and to advise employees and job applicants of the protections afforded by the Act.

(3) Number of Small Entities Covered Under Rule

This interim final rule is applicable to all private sector employers engaged in or affecting "commerce" or in the production of goods for "commerce". The scope of the term "commerce" is accorded the same meaning as provided by section 3(b) of the Fair Labor Standards Act of 1938 (29 U.S.C. 203(b)). Approximately 6.5 million employers are covered by these regulations, and the majority of such employers would be classified as small entities. In addition, these regulations contain provisions applying to over 3,500 polygraph examiners and an undetermined number of others who administer lie detector-type tests, most of which are prohibited by the Act. It is estimated that nearly all

of these examiners are either individual practitioners or associated with firms that would be classified as small entities.

(4) Reporting, Recordkeeping and Other Compliance Requirements of the Rule

The interim final rule establishes recordkeeping requirements for employers with respect to the maintenance and preservation of records for each polygraph test administered, as well as for each polygraph examiner who administers such tests on behalf of employers.

(5) Relevant Federal Rules Duplicating, Overlapping or Conflicting With the Rule

There is no duplication of existing Wage-Hour requirements, nor is similar information required by any other Federal agency or statute.

(6) Differing Compliance and Recordkeeping Requirements

The language sets forth in this interim final regulation closely adheres to the requirements imposed by the language of the Act and accompanying legislative history. The burdens imposed by these requirements on employers, and the polygraph examiners used by employers, are those imposed by statute, and those necessary to enforce the statute.

However, in developing this interim final rule, consideration was given to requiring a standard form for written statements which employers must provide to examinees, in certain instances, as a condition for administering polygraph tests under the several exemptions to the Act's general prohibition of such tests. For example, an employer is required to furnish an employee with a written statement setting the employee's rights under the law, prior to administering a polygraph test. It was concluded that employers, especially small entities, should have the flexibility to formulate and maintain such required written statements in any order or form deemed most appropriate to their needs, and that standard formats would not be required. However, to assist such employers, a sample format is set forth in the Appendix to this Part.

(7) Clarification, Consolidation and Simplification of Compliance and Reporting Requirements

As noted above, the recordkeeping requirements in this interim final rule are those imposed by statute, and those necessary to determine compliance with the Act. Employers are permitted to use

any format that meets enforcement and compliance needs.

(8) Use of Other Standards

Appropriate alternative standards that would impose fewer regulatory burdens on covered employers, especially small entities, are not available.

(9) Exemptions of Small Entities from Coverage of the Rule

An exemption from the requirements of the interim final rule for small entities is not permitted by the provisions of the Act.

Publication as an Interim Final Rule

Request for Comments

The Secretary has determined that the public interest requires the immediate issuance of these interim final regulations in order to comply with the statutory requirement that regulations be issued well in advance of the effective date of the Act. Insufficient time existed since the enactment of the EPPA for the Department to issue an in-depth proposal for comments, review the comments, and promulgate a final rule in the time provided by the Act.

The failure to have this rule in place substantially in advance of the effective date of the Act (December 27, 1988) would lead to unnecessary, unwarranted and potentially costly uncertainty on the part of affected employers, employees, job applicants, and polygraph examiners, concerning the scope of the statutory coverage and of the exemptions thereunder and concerning their rights and obligations under the Act.

Accordingly, the Secretary finds good cause, pursuant to 5 U.S.C. 553(b)(3)(B), that prior notice and public comment are impracticable and contrary to the public interest. However, interested persons are invited to submit comments on this regulation by February 27, 1989. Following evaluation of the comments received, a proposed rule or a final regulation, modified as necessary, will be published.

This document was prepared under the direction and control of Paula V. Smith, Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 801

Employment, Investigations, Labor, Law enforcement.

Signed at Washington, DC, on this 18th day of October 1988.

Ann McLaughlin,
Secretary of Labor.

Fred W. Alvarez,
Assistant Secretary for Employment Standards.

Paula V. Smith,
Administrator, Wage and Hour Division.

Accordingly, Title 29, Chapter V, of the Code of Federal Regulations is amended by adding a new Subchapter C consisting of Part 801 to read as follows.

SUBCHAPTER C—OTHER LAWS

PART 801—APPLICATION OF THE EMPLOYEE POLYGRAPH PROTECTION ACT OF 1988

Subpart A—General

- Sec.
- 801.1 Purpose and scope.
 - 801.2 Definitions.
 - 801.3 Coverage.
 - 801.4 Prohibitions on lie detector use.
 - 801.5 Effect on other laws or agreements.
 - 801.6 Notice of protection.
 - 801.7 Authority of the Secretary.

Subpart B—Exemptions

- 801.10 Exclusion for public sector employers.
- 801.11 Exemption for national defense and security.
- 801.12 Exemption for employers conducting investigations of economic loss or injury.
- 801.13 Exemption for employers authorized to manufacture, distribute, or dispense controlled substances.
- 801.14 Exemption for employers providing security services.

Subpart C—Restrictions on Polygraph Usage Under Exemptions

- 801.20 Adverse employment action under ongoing investigation exemption.
- 801.21 Adverse employment action under security service and controlled substance exemptions.
- 801.22 Rights of examinee.
- 801.23 Qualifications of and requirements for examiners.

Subpart D—Recordkeeping and Disclosure Requirements

- 801.30 Records to be preserved for 3 years.
- 801.35 Disclosure of test information.

Subpart E—Enforcement

- 801.40 General.
- 801.41 Representation of the Secretary.
- 801.42 Civil money penalties—assessment.
- 801.43 Civil money penalties—payment and collection.

Subpart F—Administrative Proceedings

General

- 801.50 Applicability of procedures and rules.

Procedures Relating to Hearing

- 801.51 Written notice of determination required.

- 801.52 Contents of notice.
- 801.53 Request for hearing.

Rules of Practice

- 801.58 General.
- 801.59 Service and computation of time.
- 801.60 Commencement of proceeding.
- 801.61 Designation of record.
- 801.62 Caption of proceeding.

Referral for Hearing

- 801.63 Referral to Administrative Law Judge.
- 801.64 Notice of docketing.

Procedures Before Administrative Law Judge

- 801.65 Appearances; representation of the Department of Labor.
- 801.66 Consent findings and order.
- 801.67 Decision and Order of Administrative Law Judge.

Modification or Vacation of Decision and Order of Administrative Law Judge

- 801.68 Authority of the Secretary.
- 801.69 Procedures for initiating review.
- 801.70 Implementation by the Secretary.
- 801.71 Filing and service.
- 801.72 Responsibility of the Office of Administrative Law Judges.
- 801.73 Final decision of the Secretary.

Record

- 801.74 Retention of official record.
- 801.75 Certification of official record.

Appendix A—Notice to examine

Authority: Pub. L. 100-347, 102 Stat. 646, 29 U.S.C. 2001-2009.

Subpart A—General

§ 801.1 Purpose and scope.

(a) Effective December 27, 1988, the Employee Polygraph Protection Act of 1988 (EPPA or the Act) prohibits most private employers (Federal, State, and local government employers are exempted from the Act) from using any lie detector tests either for pre-employment screening or during the course of employment. Polygraph tests, but no other types of lie detector tests, are permitted under limited circumstances subject to certain restrictions. The purpose of this part is to set forth the regulations to carry out the provisions of EPPA.

(b) The regulations in this part are divided into six subparts. Subpart A contains the provisions generally applicable to covered employers, including the requirements relating to the prohibitions on lie detector use and the posting of notices. Subpart A also sets forth interpretations regarding the effect of section 10 of the Act on other laws or collective bargaining agreements. Subpart B sets forth rules regarding the statutory exemptions from application of the Act. Subpart C sets forth the restrictions on polygraph usage under such exemptions. Subpart D sets forth the recordkeeping requirements

and the rules on the disclosure of polygraph test information. Subpart E deals with the authority of the Secretary of Labor and the enforcement provisions under the Act. Subpart F contains the procedures and rules of practice necessary for the administrative enforcement of the Act.

§ 801.2 Definitions.

For purposes of this part:

(a) "Act" or "EPPA" means the Employee Polygraph Protection Act of 1988 (Pub. L. 100-347, 102 Stat. 646, 29 U.S.C. 2001-2009).

(b) (1) The term "commerce" has the meaning provided in section 3(b) of the Fair Labor Standards Act of 1938 (29 U.S.C. 203(b)). As so defined, "commerce" means trade, commerce, transportation, transmission, or communication among the several States or between any State and any place outside thereof.

(2) The term "State" means any of the fifty States and the District of Columbia and any Territory or possession of the United States.

(c) The term "employer" means any person acting directly or indirectly in the interest of an employer in relation to an employee or prospective employee. A polygraph examiner either employed for or whose services are retained for the sole purpose of administering polygraph tests ordinarily would not be deemed an "employer" with respect to the examinees.

(d) (1) The term "lie detector" means a polygraph, deceptiongraph, voice stress analyzer, psychological stress evaluator, or any other similar device (whether mechanical or electrical) that is used, or the results of which are used, for the purpose of rendering a diagnostic opinion regarding the honesty or dishonesty of an individual.

(2) The term "lie detector" does not include medical tests used to determine the presence or absence of controlled substances or alcohol in bodily fluids. Also not included in the definition of "lie detector" are written or oral tests commonly referred to as "honesty" or "paper and pencil" tests, machine-scored or otherwise.

(e) The term "polygraph" means an instrument that—

(1) Records continuously, visually, permanently, and simultaneously changes in cardiovascular, respiratory, and electrodermal patterns as minimum instrumentation standards; and

(2) Is used, or the results of which are used, for the purpose of rendering a diagnostic opinion regarding the honesty or dishonesty of an individual.

(f) The terms "manufacture", "dispense", "distribute", and "deliver" have the meanings set forth in the Controlled Substances Act, 21 U.S.C. 802.

(g) The term "Secretary" means the Secretary of Labor or authorized representative.

(h) "Employment Standards Administration" means the agency within the Department of Labor, which includes the Wage and Hour Division.

(i) "Wage and Hour Division" means the organizational unit in the Employment Standards Administration of the Department of Labor to which is assigned primary responsibility for enforcement and administration of the Act.

(j) "Administrator" means the Administrator of the Wage and Hour Division, or authorized representative.

§ 801.3 Coverage.

Any employer engaged in or affecting commerce or in the production of goods for commerce is subject to the provisions of the Act, unless otherwise exempt pursuant to section 7 of the Act and §§ 801.10 through 801.14 of this part.

§ 801.4 Prohibitions on lie detector use.

Section 3 of EPPA provides that, unless otherwise exempt pursuant to section 7 of the Act and §§ 801.10 through 801.14 of this part, covered employers are prohibited from:

(a) Requiring, requesting, suggesting or causing, directly or indirectly, any employee or prospective employee to take or submit to a lie detector test;

(b) Using, accepting, or inquiring about the results of a lie detector test of any employee or prospective employee; and

(c) Discharging, disciplining, discriminating against, denying employment or promotion, or threatening any employee or prospective employee to take such action for refusal or failure to take or submit to such test, on the basis of the results of a test, for filing a complaint, for testifying in any proceeding, or for exercising any rights afforded by the Act.

§ 801.5 Effect on other laws or agreements.

(a) Section 10 of EPPA provides that the Act, except for subsections (a), (b), and (c) of section 7, does not preempt any provision of a State or local law, or any provision of a collective bargaining agreement, that prohibits lie detector tests or is more restrictive with respect to the use of lie detector tests.

(b) (1) This provision applies to all aspects of the use of lie detector tests, including procedural safeguards, the use

of test results, the rights and remedies provided examinees, and the rights, remedies, and responsibilities of examiners and employers.

(2) For example, if the State prohibits the use of polygraphs in all private employment, polygraph examinations could not be conducted pursuant to the limited exemptions provided in the Act; a collective bargaining agreement that provides greater protection to an examinee would apply in addition to the protection provided in the Act; or more stringent licensing or bonding requirements in a State law would apply in addition to the Federal bonding requirement.

(3) On the other hand, industry exemptions and applicable restrictions thereon, provided in EPPA, would preempt less restrictive exemptions established by State law for the same industry, e.g., random testing of current employees in the drug industry not prohibited by State law but limited by this Act to tests administered in connection with ongoing investigations.

(c) EPPA does not impede the ability of State and local governments to enforce existing statutes or to enact subsequent legislation restricting the use of lie detectors with respect to public employees.

(d) Nothing in section 10 of the Act restricts or prohibits the Federal Government from administering polygraph tests to its own employees or to experts, consultants, or employees of contractors, as provided in subsections 7(b) and 7(c) of the Act, and § 801.11 of this part.

§ 801.6 Notice of protection.

Every employer subject to EPPA shall post and keep posted on its premises a notice explaining the Act, as prescribed by the Secretary. Such notice must be posted in a prominent and conspicuous place in every establishment of the employer where it can readily be observed by employees and applicants for employment. Copies of such notice may be obtained from local offices of the Wage and Hour Division.

§ 801.7 Authority of the Secretary.

(a) Pursuant to section 5 of the Act, the Secretary is authorized to:

(1) Issue such rules and regulations as may be necessary or appropriate to carry out the Act;

(2) Cooperate with regional, State, local, and other agencies, and cooperate with and furnish technical assistance to employers, labor organizations, and employment agencies to aid in effectuating the purposes of the Act; and

(3) Make investigations and inspections as necessary or appropriate,

through complaint or otherwise, including inspection of such records (and copying or transcription thereof), questioning of such persons, and gathering such information as deemed necessary to determine compliance with the Act or these regulations; and

(4) Require the keeping of records necessary or appropriate for the administration of the Act.

(b) Section 5 of the Act also grants the Secretary authority to issue subpoenas requiring the attendance and testimony of witnesses or the production of any evidence in connection with any investigation or hearing under the Act. The Secretary may administer oaths, examine witnesses, and receive evidence. For the purpose of any investigation or hearing provided for in the Act, the authority contained in sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49, 50), relating to the attendance of witnesses and the production of books, papers, and documents, shall be available to the Secretary.

(c) In case of disobedience to a subpoena, the Secretary may invoke the aid of a United States District Court which is authorized to issue an order requiring the person to obey such subpoena.

(d) Any person may report a violation of the Act or these regulations to the Secretary by advising any local office of the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, or any authorized representative of the Administrator. The office or person receiving such a report shall refer it to the appropriate office of the Wage and Hour Division, Employment Standards Administration, for the region or area in which the reported violation is alleged to have occurred.

(e) The Secretary shall conduct investigations in a manner which, to the extent practicable, protects the confidentiality of any complainant or other party who provides information to the Secretary in good faith.

(f) It is a violation of these regulations for any person to resist, oppose, impede, intimidate, or interfere with any official of the Department of Labor assigned to perform an investigation, inspection, or law enforcement function pursuant to the Act during the performance of such duties.

Subpart B—Exemptions

§ 801.10 Exclusion for public sector employers.

(a) Section 7(a) provides an exclusion from the Act's coverage for the United

States Government, any State or local government, or any political subdivision of a State or local government, acting in the capacity of an employer. This exclusion from the Act also extends to any interstate governmental agency.

(b) The term "United States Government" means any agency or instrumentality, civilian or military, of the executive, legislative, or judicial branches of the Federal Government, and includes independent agencies, wholly-owned government corporations, and nonappropriated fund instrumentalities.

(c) This exclusion from the Act applies only to the Federal, State, and local government entity. It does not extend to contractors or nongovernmental agents of a government entity.

§ 801.11 Exemption for national defense and security.

(a) The Exemptions allowing for the administration of polygraph tests in the following paragraphs (b) through (e) of this section apply only to the Federal Government; they do not allow private employers/contractors to administer such test.

(b) Section 7(b)(1) provides that nothing in the Act shall be construed to prohibit the administration of any lie detector test by the Federal Government, in the performance of any counterintelligence function, to any expert, consultant or employee of any contractor to the Department of Defense; or the Department of Energy, in connection with the atomic energy defense activities of such Department.

(c) Section 7(b)(2)(A) provides that nothing in the Act shall be construed to prohibit the administration of any lie detector test by the Federal Government, in the performance of any intelligence or counterintelligence function of the National Security Agency, the Defense Intelligence Agency, or the Central Intelligence Agency, to any individual employed by, assigned to, or detailed to any such agency; or any expert or consultant under contract to any such agency; or any individual applying for a position in any such agency; or any individual assigned to a space where sensitive cryptologic information is produced, processed, or stored for any such agency.

(d) Section 7(b)(2)(B) provides that nothing in the Act shall be construed to prohibit the administration of any lie detector test by the Federal Government, in the performance of any intelligence or counterintelligence function, to any expert, or consultant (or employee of such expert or consultant)

under contract with any Federal Government department, agency, or program whose duties involve access to information that has been classified at the level of top secret or designated as being within a special access program under section 4.2 (a) of Executive Order 12356 (or a successor Executive Order).

(e) Section 7(c) provides that nothing in the Act shall be construed to prohibit the administration of any lie detector test by the Federal Government, in the performance of any counterintelligence function, to any employee of a contractor of the Federal Bureau of Investigation of the Department of Justice who is engaged in the performance of any work under a contract with the Bureau.

(f) "Counterintelligence" for purposes of the above paragraphs means information gathered and activities conducted to protect against espionage and other clandestine intelligence activities, sabotage, terrorist activities, or assassinations conducted for or on behalf of foreign governments, or foreign or domestic organizations or persons.

(g) Lie detector tests of persons described in the above paragraphs shall be administered in accordance with applicable Department of Defense directives and regulations, or other regulations and directives governing the use of such tests by the United States Government, as applicable.

§ 801.12 Exemption for employers conducting investigations of economic loss or injury.

(a) Section 7(d) of the Act provides a limited exemption from the general prohibition on lie detector use in private employment settings for employers conducting ongoing investigations of economic loss or injury to the employer's business. An employer may request an employee, subject to the conditions set forth in sections 8 and 10 of the Act and §§ 801.20, 801.22, 801.23, and 801.35 of this part, to submit to a polygraph test, but no other type of lie detector test, only if—

(1) The test is administered in connection with an ongoing investigation involving economic loss or injury to the employer's business, such as theft, embezzlement, misappropriation or an act of industrial espionage or sabotage;

(2) The employee has access to the property that is the subject of the investigation;

(3) The employer has a reasonable suspicion that the employee was involved in the incident or activity under investigation;

(4) The employer provides the examinee with a statement, in a

language understood by the examinee, prior to the test which fully explains with particularity the specific incident or activity being investigated and the basis for testing particular employees and which contains, at a minimum:

(i) An identification with particularity of the specific economic loss or injury to the business of the employer;

(ii) A statement specifically describing the employee's access to the property that is the subject of the investigation;

(iii) A statement describing in detail the basis of the employer's reasonable suspicion that the employee was involved in the incident or activity under investigation; and

(iv) Signature of a person (other than a polygraph examiner) authorized to legally bind the employer; and

(5) The employer retains a copy of the statement described in paragraph (a)(4) of this section for at least 3 years and makes it available for inspection by the Wage and Hour Division on request. (See § 801.30(a).)

(b) For the exemption to apply, the condition of an "ongoing investigation" must be met. As used in section 7(d) of the Act, the ongoing investigation must be of a specific incident or activity. Thus, for example, an employer may not request that an employee or employees submit to a polygraph test in an effort to determine whether or not any thefts have occurred. Such random testing by an employer is specifically precluded by the Act. Further, by limiting the exemption to a specific incident or activity, an employer is precluded from using the exemption in situations where the so-called "ongoing investigation" is continuous. For example, the fact that items in inventory are frequently missing from a warehouse would not be a sufficient basis for administering a polygraph test. Even if the employer can establish that unusually high amounts of inventory are missing from the warehouse in a given month, this, in and of itself, would not be sufficient basis to meet the specific incident requirement without evidence of intentional wrongdoing. Administering a polygraph test in such circumstances, without identification of a specific incident or activity and a "reasonable suspicion that the employee was involved" would amount to little more than a fishing expedition.

(c) (1) The term "economic loss or injury to the employer's business" includes losses or injuries resulting from theft, embezzlement, misappropriation, industrial espionage or sabotage. These examples, cited in the Act, are intended to be illustrative and not exhaustive. Other specific incidents which would

meet the economic loss or injury requirement include check-kiting, money laundering, or the misappropriation of confidential or trade secret information. Similarly, instances such as theft from property managed by an employer, or property held by an employer as a fiduciary or custodian, would meet the required injury standard.

(2) The economic loss must result from intentional wrongdoing. Thus, losses which would not serve as a basis for the administration of a polygraph test include those apparently unintentional losses stemming from a truck, car, workplace or other similar type accidents. Any economic loss incident to lawful union or employee activity also would not satisfy this requirement.

(3) It is the business of the employer which must suffer the economic loss or injury. Thus, a theft committed by one employee against another employee of the same employer would not satisfy the requirement.

(d) While nothing in the Act prohibits the use of medical tests to determine the presence of controlled substances or alcohol in bodily fluids, the section 7(d) exemption does not permit the use of a polygraph test to learn whether an employee has used drugs or alcohol, even where such possible use may have contributed to an economic loss to the employer (e.g., an accident involving a company vehicle).

(e) Section 7(d)(2) provides that, as a condition for the use of the exemption, the employee must have had access to the property that is the subject of the investigation.

(1) The word "access", as used in section 7(d)(2), refers to the opportunity which an employee had to cause, or to aid or abet in causing, the specific economic loss or injury under investigation.

The term "access", thus, includes more than direct or physical contact during the course of employment. For example, all employees working in or with authority to enter a warehouse storage area have "access" to the property in the warehouse. All employees with the combination to a safe have "access" to the property in a locked safe. Employees also have "access" who have the ability to divert possession or otherwise affect the disposition of the property that is the subject of investigation. For example, a bookkeeper in a jewelry store with access to inventory records may aid or abet a clerk who steals an expensive watch by removing the watch from the employer's inventory records. In such a situation, it is clear that the bookkeeper effectively has "access" to the property that is the subject of the investigation.

(2) As used in section 7(d)(2), "property" refers to specifically identifiable property, but also includes such things of value as security codes and computer data, and proprietary financial or technical information which by its availability to competitors or others would cause economic harm to the employer.

(f)(1) As used in section 7(d)(3), the term "reasonable suspicion" refers to an observable, articulable basis in fact which indicates that a particular employee was involved in, or responsible for, an economic loss. Thus, for example, access in the sense of possible or potential opportunity, standing alone, does not constitute a basis for "reasonable suspicion". Information from a co-worker, or an employee's behavior, demeanor, or conduct may be factors in the basis for reasonable suspicion. Likewise, inconsistencies between facts, claims, or statements that surface during an investigation can serve as a sufficient basis for reasonable suspicion. While access or opportunity, standing alone, does not constitute a basis for reasonable suspicion, the totality of circumstances surrounding the access or opportunity (such as its unauthorized or unusual nature) may constitute a factor in determining whether there is a reasonable suspicion.

(2) For example, in an investigation of a theft of an expensive piece of jewelry, an employee authorized to open the establishment's safe no earlier than 9:00 a.m., in order to place the jewelry in a window display case, is observed opening the safe at 7:30 a.m. In such a situation, the opening of the safe by the employee one and one-half hours prior to the specified time may serve as the basis for reasonable suspicion. On the other hand, in the example given, if the employer asked the employee to bring the piece of jewelry to his or her office at 7:30, and the employee then opened the safe and reported the jewelry missing, such access, standing alone, would not constitute a basis for reasonable suspicion that the employee was involved in the incident.

(3) The employer has the burden of establishing that the specific individual or individuals to be tested are "reasonably suspected" of involvement in the specific economic loss or injury for the requirement in section 7(d)(3) to be met.

(g)(1) As discussed in paragraph (a)(4) of this section, section 7(d)(4) of the Act sets forth what information, at a minimum, must be provided to an employee if the employer wishes to claim the exemption.

(2) The statement required under paragraph (a)(4) of this section must be received by the employee at least 48 hours prior to the time of the examination. This will provide the employee with adequate pre-test notice of the specific incident or activity being investigated and afford the employee sufficient time prior to the test to obtain and consult with legal counsel or an employee representative.

(3) The statement to be provided to the employee must set forth with particularity the specific incident or activity being investigated and the basis for testing particular employees. However, section 7(d)(4)(A) requires specificity beyond the mere assertion of general statements regarding economic loss, employee access, and reasonable suspicion. For example, an employer's assertion that an expensive watch was stolen, and that the employee had access to the watch and is therefore a suspect, would not meet the "with particularity" criterion. If the basis for an employer's requesting an employee (or employees) to take a polygraph test cannot be articulated, and reduced to writing, then the standard would not be met. The identity of a co-worker or other individual providing information used to establish reasonable suspicion need not be revealed in the statement.

(4) It is further required that the statement provided to the examinee be signed by a person authorized to legally bind the employer. The standard would not be met if the person signing the statement is not authorized to legally bind the employer, and accordingly the exemption would not apply in such a case.

(h) Polygraph tests administered pursuant to this exemption are subject to the limitations set forth in sections 8 and 10 of the Act, as discussed in §§ 801.20, 801.22, 801.23, and 801.35 of this part. As provided in these sections, the exemption will apply only if certain requirements are met. Failure to satisfy any of the specified requirements nullifies the statutory authority for polygraph test administration and may subject the employer to the assessment of civil money penalties and other remedial actions, as provided for in section 6 of the Act (see Subpart E, § 801.42 of this part). The administration of such tests is also subject to State or local laws, or collective bargaining agreements, which may either prohibit lie detector tests, or contain more restrictive provisions with respect to polygraph testing.

§ 801.13 Exemption for employers authorized to manufacture, distribute, or dispense controlled substances.

(a) Section 7(f) provides an exemption from the Act's general prohibition regarding the use of polygraph tests for employers authorized to manufacture, distribute, or dispense a controlled substance listed in schedule I, II, III, or IV of section 202 of the Controlled Substances Act (21 U.S.C. 812). This exemption permits the administration of polygraph tests, subject to the conditions set forth in sections 8 and 10 of the Act and §§ 801.21, 801.22, 801.23, and 801.35 of this part, to:

(1) A prospective employee who would have direct access to the manufacture, storage, distribution, or sale of any such controlled substance; or

(2) A current employee if the following conditions are met:

(i) The test is administered in connection with an ongoing investigation of criminal or other misconduct involving, or potentially involving, loss or injury to the manufacture, distribution, or dispensing of any such controlled substance by such employer; and

(ii) The employee had access to the person or property that is the subject of the investigation.

(b)(1) The terms "manufacture", "distribute", "distribution", "dispense", "storage", and "sale", for the purposes of this exemption, are construed within the meaning of the Controlled Substances Act (21 U.S.C. 801 *et seq.*), as administered by the Drug Enforcement Administration (DEA), U.S. Department of Justice.

(2) The exemption in section 7(f) of the Act applies only to employers who are authorized by DEA to manufacture, distribute, or dispense a controlled substance. Section 302 of the Controlled Substances Act (21 U.S.C. 822) requires every person who manufactures, distributes, or dispenses any controlled substance to register with the Attorney General (i.e., with DEA). Common or contract carriers and warehouses whose possession of the controlled substance is in the usual course of their business or employment are not required to register. Since this exemption is intended to apply only to employees and prospective employees of persons or entities registered with DEA, and is not intended to apply to truck drivers employed by persons or entities who are not so registered, it has no application to employees of common or contract carriers or public warehouses. Truck drivers and warehouse employees of the persons or entities registered with DEA and authorized to manufacture, distribute, or dispense controlled

substances, are within the scope of the exemption where they have direct access or access to the controlled substances, as discussed below.

(c) In order for a polygraph examination to be performed, section 7(f) of the Act requires that a prospective employee have "direct access" to the controlled substance(s) manufactured, dispensed, or distributed by the employer. Where a current employee is to be tested as a part of an ongoing investigation, section 7(f) requires that the employee have "access" to the person or property that is the subject of the investigation.

(1) A prospective employee would have "direct access" if the position being applied for has responsibilities which include contact with or which affect the disposition of a controlled substance, including participation in the process of obtaining, dispensing, or otherwise distributing a controlled substance. This includes contact or direct involvement in the manufacture, storage, testing, distribution, sale or dispensing of a controlled substance and may include, for example, packaging, repackaging, ordering, licensing, shipping, receiving, taking inventory, providing security, prescribing, and handling of a controlled substance. A prospective employee would have "direct access" if the described job duties would give such person access to the products in question, whether such employee would be in physical proximity to controlled substances or engaged in activity which would permit the employee to divert such substances to his or her possession.

(2) A current employee would have "access" within the meaning of section 7(f) if the employee had access to the specific person or property which is the subject of the on-going investigation, as discussed in § 801.12(e) of this part. Thus, to test a current employee, the employee need not have had "direct" access to the controlled substance, but may have had only infrequent, random, or opportunistic access. Such access would be sufficient to test the employee if the employee could have caused, or could have aided or abetted in causing, the loss of the specific property which is the subject of the investigation. In addition, a maintenance worker in a drug warehouse, whose job duties include the cleaning of areas where the controlled substances which are the subject of the investigation were present, but whose job duties do not include the handling of controlled substances, would be deemed to have "access", but normally not "direct access", to the controlled substances. On the other hand, a drug warehouse

truck loader, whose job duties include the handling of outgoing shipment orders which contain controlled substances, would have "direct access" to such controlled substances. A pharmacy department in a supermarket is another common situation which is useful in illustrating the distinction between "direct access" and "access". Store personnel receiving pharmaceutical orders, i.e., the pharmacist, pharmacy intern, and other such employees working in the pharmacy department, would ordinarily have "direct access" to controlled substances. Other store personnel whose job duties and responsibilities do not include the handling of controlled substances but who had occasion to enter the pharmacy department where the controlled substances which are the subject of the investigation were stored, such as maintenance personnel or pharmacy cashiers, would have "access". Certain other store personnel whose job duties do not permit or require entrance into the pharmacy department for any reason, such as produce or meat clerks, checkout cashiers, or baggers, would not ordinarily have "access" of any type. In the case of "direct access", the prospective employee's access to controlled substances would be as a part of the manufacturing, dispensing or distribution process, while a current employee's "access" to the controlled substances which are the subject of the investigation need only be opportunistic.

(d) The term "prospective employee", for the purposes of this section, includes a current employee who presently holds a position which does not entail direct access to controlled substances, and therefore is outside the scope of the exemption's provisions for preemployment polygraph testing, provided the employee has applied for and is being considered for transfer or promotion to another position which entails such direct access. For example, an office secretary may apply for promotion to a position in the vault or cage areas of a drug warehouse, where controlled substances are kept. In such a situation, the current employee would be deemed a "prospective employee" for the purposes of this exemption, and thus would be subject to preemployment polygraph screening, at the time of such a change in position. However, any adverse action which is based in part on a polygraph test against a current employee who is treated as a "prospective employee" may be taken only with respect to the prospective position and may not affect the

employee's employment in the current position.

(e) Section 7(f) of the Act makes no specific reference to a requirement that employers provide current employees with a written statement prior to polygraph testing. Thus, employers to whom this exemption is available are not required to furnish a written statement such as that specified in section 7(d) of the Act and § 801.12(a)(4) of this part.

(f) For the section 7(f) exemption to apply, the polygraph testing of current employees must be administered "in connection with an ongoing investigation of criminal or other misconduct involving, or potentially involving, loss or injury to the manufacture, distribution, or dispensing of any such controlled substance by such employer * * *".

(1) Current employees may only be administered polygraph tests in connection with an ongoing investigation, relating to a specific incident or activity, or potential incident or activity, as discussed in § 801.12(b) of this part. Thus an employer is precluded from using the exemption in connection with continuing investigations or on a random basis to determine if thefts are occurring.

(2) In addition, the test must be administered in connection with loss or injury, or potential loss or injury, to the manufacture, distribution, or dispensing of a controlled substance.

(i) Retail drugstores and wholesale drug warehouses typically carry inventory of so-called health and beauty aids, cosmetics, over-the-counter drugs, and a variety of other similar products, in addition to their product lines of controlled drugs. The noncontrolled products usually constitute the majority of such firms' sales volumes. An economic loss or injury related to such noncontrolled substances would not constitute a basis of applicability of the section 7(f) exemption. For example, an investigation into the theft of a gross of cosmetic products could not be a basis for polygraph testing under section 7(f), but the theft of a container of valium could be.

(ii) Polygraph testing, with respect to an ongoing investigation concerning products other than controlled substances might be initiated under section 7(d) of the Act and § 801.12 of this part. However, the exemption in section 7(f) of the Act and this section is limited solely to losses or injury associated with controlled substances.

(g) Polygraph tests administered pursuant to this exemption are subject to the limitations set forth in sections 8 and 10 of the Act, as discussed in

§§ 801.21, 801.22, 801.23, and 801.35 of this part. As provided in these sections, the exemption will apply only if certain requirements are met. Failure to satisfy any of the specified requirements nullifies the statutory authority for polygraph test administration and may subject the employer to the assessment of civil money penalties and other remedial actions, as provided for in section 6 of the Act (see Subpart E, § 801.42 of this part). The administration of such tests is also subject to State or local laws, or collective bargaining agreements, which may either prohibit lie detector tests, or contain more restrictive provisions with respect to polygraph testing.

§ 801.14 Exemption for employers providing security services.

(a) Section 7(e) of the Act provides an exemption from the general prohibition against polygraph tests for certain armored car, security alarm, and security guard employers. Subject to the conditions set forth in sections 8 and 10 of the Act and §§ 801.21, 801.22, 801.23, and 801.35 of this part, section 7(e) permits the use of polygraph tests on prospective employees provided that such employers have as their primary business purpose the providing of armored car personnel, personnel engaged in the design, installation, and maintenance of security alarm systems, or other uniformed or plainclothes security personnel; and provided the prospective employees are being hired to protect:

(1) Facilities, materials, or operations having a significant impact on the health or safety of any State or political subdivision thereof, or the national security of the United States, such as—

(i) Facilities engaged in the production, transmission, or distribution of electric or nuclear power,

(ii) Public water supply facilities,

(iii) Shipments or storage of radioactive or other toxic waste materials, and

(iv) Public transportation; or

(2) Currency, negotiable securities, precious commodities or instruments, or proprietary information.

(b)(1) Section 7(e) permits the administration of polygraph tests only to prospective employees. However, security service employers may administer polygraph tests to current employees in connection with an ongoing investigation, subject to the conditions of section 7(d) of the Act and § 801.12 of this part.

(2) The term "prospective employee" generally refers to an individual who is being considered for employment, for the first time, by an employer. However,

the term "prospective employee" also includes current employees under circumstances similar to those discussed in paragraph (d) of § 801.13 of this part. Thus, for example, a security guard may be hired for a job outside the scope of the exemption's provisions for pre-employment polygraph testing, such as a position at a supermarket. If subsequently this guard is transferred or promoted to a job at a nuclear power plant, this currently-employed individual would be considered to be a "prospective employee" for purposes of this exemption, at the time of such proposed transfer or promotion. However, any adverse action which is based in part on a polygraph test against a current employee who is treated as a "prospective employee" may be taken only with respect to the prospective position and may not affect the employee's employment in the current position.

(c) Section 7(e) applies to any private employer whose "primary business purpose" consists of providing armored car personnel, personnel engaged in the design, installation, and maintenance of security alarm systems, or other uniformed or plainclothes security personnel. Thus, the exemption is limited to firms primarily in the business of providing such security services to others. (For example, a utility company which employs its own security personnel could not qualify.) In the case of diversified firms, the term "primary business purpose" shall mean that at least 50% of the employer's annual dollar volume of business is derived from the provision of the types of security services specifically identified in section 7(e).

(d)(1) As used in section 7(e)(1)(A), the terms "facilities, materials, or operations having a significant impact on the health or safety of any State or political subdivision thereof, or the national security of the United States" include protection of electric or nuclear power plants, public water supply facilities, radioactive or other toxic waste shipments or storage, and public transportation. These examples are intended to be illustrative, and not exhaustive. However, the types of "facilities, materials, or operations" within the scope of the exemption are not to be construed so broadly as to include low priority or minor security interests. The "facilities, materials, or operations" in question only consist of those having a "significant impact" on public health or safety, or national security. However, the "facilities, materials, or operations" may be either privately or publicly owned.

(2) The specific "facilities, materials, or operations" contemplated by this exemption would include those against which acts of sabotage, espionage, terrorism, or other hostile, destructive, or illegal acts could have a serious effect on the general public's safety or health, or national security. In addition to the specific examples set forth in the Act, the terms would include:

(i) Facilities, materials, and operations owned or leased by Federal, State, or local governments, including instrumentalities or interstate agencies thereof, for which an authorized public official has determined that a need for security exists, utilizing private armored car, security alarm system, or uniformed or plainclothes security personnel, or a combination thereof, such as:

- (A) Government office buildings;
- (B) Prisons and correction facilities;
- (C) Public schools;
- (D) Public libraries;
- (E) Water supply;
- (F) Military reservations, installations, posts, camps, arsenals, laboratories, and other similar facilities vital to defense and security;

(ii) Commercial and industrial assets and operations which—

(A) Are designated in writing by an appropriate Federal agency to be vital to national security interests (such as those of defense contractors and researchers), including factories, plants, buildings, or structures used for researching, designing, testing, manufacturing, producing, processing, repairing, assembling, storing, or distributing products or components related to the national defense; or

(B) Would pose a serious threat to public health or safety in the event of a breach of security (such as a plant engaged in the manufacture or processing of hazardous materials or chemicals);

(iii) Public and private energy and precious mineral facilities, supplies, and reserves, including—

(A) Public or private power plants and utilities;

(B) Oil or gas refineries and storage facilities;

(C) Strategic petroleum reserves; and

(D) Major dams, such as those which provide hydroelectric power; or

(iv) Major public or private transportation and communication facilities and operations, including—

(A) Airports;

(B) Train terminals, depots, and switching and control facilities;

(C) Major bridges and tunnels;

(D) Communications centers, such as receiving and transmission centers, and control centers; and

(E) Transmission and receiving operations for radio, television, and satellite signals; or

(v) The Federal Reserve System and stock and commodity exchanges;

(vi) Hospitals and health research facilities; and

(vii) Large public events, such as political conventions and major parades, concerts, and sporting events.

(3) Whether given "facilities, materials, or operations" fall within the contemplated purview of this exemption will be determined by the Administrator on request prior to the administration of the polygraph test, based on all the facts and circumstances. It is not possible to exhaustively account for all "facilities, materials, or operations" which fall within the purview of section 7(e)(1)(A). While it is likely that additional entities may fall within the exemption's scope, any such "facilities, materials, or operations" must meet the "significant impact" test. Thus, "facilities, materials, or operations" which would be of vital importance during periods of war or civil emergency, or whose sabotage would greatly affect the public health or safety, could fall within the scope of the term "significant impact".

(e) Section 7(e)(1)(B) of the Act extends the exemption to firms whose function includes protection of "currency, negotiable securities, precious commodities or instruments, or proprietary information". These terms collectively are construed to be assets handled by financial institutions such as banks, credit unions, savings and loan institutions, stock and commodity exchanges, brokers, or security dealers. These terms also refer to assets which are typically handled by, protected for and transported between and among commercial and financial institutions. Services provided by the armored car industry are thus clearly within the scope of the exemption, as are security alarm and security guard services provided to financial institutions of the type referred to above. However, security alarm or guard services provided to private homes, or to businesses not primarily engaged in handling, trading, transferring, or storing currency, negotiable securities, precious commodities or instruments, or proprietary information, are outside the scope of the exemption. This is true even though such places may physically house some such assets.

(f) An employer who falls within the scope of the exemption is one "whose function includes" protection of "facilities, materials, or operations", discussed in paragraph (e) of this section or of "currency, negotiable securities, precious commodities or

instruments, or proprietary information" discussed in paragraph (f) of this section. Thus, assuming that the employer has met the "primary business purpose" test, as set forth in paragraph (d) of this section, the employer's operations then must simply "include" protection of at least one of the facilities within the scope of the exemption.

(g)(1) Section 7(e)(2) provides that the exemption shall not apply if a polygraph test is administered to a prospective employee who would not be employed to protect the "facilities, materials, operations, or assets" referred to in section 7(e)(1) of the Act, and discussed in paragraphs (e) and (f) of this section. Thus, while the exemption applies to employers whose function "includes" protection of certain facilities, employers would be permitted to administer polygraph tests only to prospective employees who are being hired to perform such functions.

(2) The phrase "employed to protect" in section 7(e)(2) has reference to a wide spectrum of prospective employees in the security industry, and includes all employees whose job duties affect the security of any qualifying "facilities, materials, operations, or assets," either directly or indirectly.

(3) In many cases, it will be readily apparent that certain positions within security companies would, by virtue of the individual's official job duties, entail "protection". For example, armored car drivers and guards, security guards, and alarm system installers and maintenance personnel all would be employed to protect in the most direct and literal sense of the term.

(4) The scope of the exemption is not limited, however, to those security personnel having direct, physical access to the facilities being protected. Various support personnel may also have "access" to the process of providing security services due to the position's exposure to knowledge of security plans and operations, employee schedules, delivery schedules, and other such activities. Where a position entails the opportunity to cause or participate in a breach of security, an employee to be hired for the position would also be deemed to be "employed to protect" the facility within the exemption's scope.

(5) For example, in the armored car industry, the duties of personnel other than guards and drivers may include taking customer orders for currency and commodity transfers, issuing security badges to guards, coordinating routes of travel and times for pick-up and delivery, issuing access codes to customers, route planning and other sensitive responsibilities. Similarly, in

the security alarm industry, several types of employees would have access to the process of providing security services, such as designers of security systems, system monitors, service technicians, and billing clerks (who may review the system design drawings to ensure proper customer billing). In the security industry, generally, administrative employees may have access to customer accounts, schedules, information relating to alarm system failures, and other security information, such as security employee absences due to illness that create "holes" in a security plan. Employees of this type are a part of the overall security services provided by the employer. Such employees possess the ability to affect, on an opportunistic basis, the security of protected operations, by virtue of the knowledge gained through their job duties.

(6) On the other hand, there are certainly some types of employees in the security industry who "would not be employed to protect" the functions within the purview of the exemption, and who would not have "access" to the process of providing security services. For example, custodial and maintenance employees typically would not have access, either directly or indirectly, to the operations or clients of the employer. Any employee whose "access" to secured areas or to sensitive information is occasional, or on a controlled basis, such as by escort, would also be outside the scope of the exemption. In cases where security service companies also provide janitorial, food and beverage, or other services unrelated to security, the exemption would clearly not extend to any employee considered for employment in such activity.

(h) Polygraph tests administered pursuant to this exemption are subject to the limitations set forth in sections 8 and 10 of the Act, as discussed in §§ 801.21, 801.22, 801.23, and 801.35 of this part. As provided in these sections, the exemption will apply only if certain requirements are met. Failure to satisfy any of the specified requirements nullifies the statutory authority for polygraph test administration and may subject the employer to the assessment of civil money penalties and other remedial actions, as provided for in section 6 of the Act (see Subpart E, § 801.42 of this part). The administration of such tests is also subject to State or local laws, or collective bargaining agreements, which may either prohibit lie detectors test, or contain more restrictive provisions with respect to polygraph testing.

Subpart C—Restrictions on Polygraph Usage Under Exemptions

§ 801.20 Adverse employment action under ongoing investigation exemption.

(a) Section 8(a)(1) of the Act provides that the limited exemption in section 7(d) of the Act and § 801.12 of this part for ongoing investigations shall not apply if an employer discharges, disciplines, denies employment or promotion or otherwise discriminates in any manner against a current employee based upon the analysis of a polygraph test chart or the refusal to take a polygraph test, without additional supporting evidence.

(b) "Additional supporting evidence", for purposes of section 8(a) of the Act, includes, but is not limited to, the following:

- (1)(i) Evidence indicating that the employee had access to the missing or damaged property that is the subject of an ongoing investigation; and
- (ii) Evidence leading to the employer's reasonable suspicion that the employee was involved in the incident or activity under investigation; or

(2) Admissions or statements made by an employee before, during or following a polygraph examination.

(c) Analysis of a polygraph test chart or refusal to take a polygraph test may not serve as a basis for adverse employment action, even with additional supporting evidence, unless the employer observes all the requirements of sections 7(d) and 8(b) of the Act, as described in §§ 801.12 and 801.22 of this part.

§ 801.21 Adverse employment action under security service and controlled substance exemptions.

(a) Section 8(a)(2) of the Act provides that the security service exemption in section 7(e) of the Act and § 801.14 of this part and the controlled substance exemption in section 7(f) of the Act and § 801.13 of this part shall not apply if an employer discharges, disciplines, denies employment or promotion, or otherwise discriminates in any manner against a current employee or prospective employee based solely on the analysis of a polygraph test chart or the refusal to take a polygraph test.

(b) Analysis of a polygraph test chart or refusal to take a polygraph test may serve as one basis for adverse employment actions of the type described in paragraph (a) of this section, *provided* that the adverse action was also based on another *bona fide* reason. For example, traditional factors such as prior employment experience, education, job performance, etc. may be used as a basis for employment

decisions. Employment decisions based on admissions or statements made by an employee or prospective employee before, during or following a polygraph examination may, likewise, serve as a basis for such decisions.

(c) Analysis of a polygraph test chart or the refusal to take a polygraph test may not serve as a basis for adverse employment action, even with another legitimate basis for such action, unless the employer observes all the requirements of section 7 (e) or (f) of the Act, as appropriate, and section 8(b) of the Act, as described in §§ 801.13, 801.14 and 801.22 of this part.

§ 801.22 Rights of examinee.

(a) Pursuant to section 8(b) of the Act, the limited exemption in section 7(d) of the Act for ongoing investigations, and the security service and controlled substance exemptions in 7 (e) and (f) of the Act (described in §§ 801.12, 801.13, and 801.14 of this part) shall not apply unless all of the requirements set forth in this section are met.

(b)(1) During all phases of the polygraph testing the person being examined has the following rights:

- (i) The examinee may terminate the test at any time;
- (ii) The examinee may not be asked any questions in a degrading or unnecessarily intrusive manner;
- (iii) The examinee may not be asked any questions dealing with:
 - (A) Religious beliefs or affiliations;
 - (B) Beliefs or opinions regarding racial matters;
 - (C) Political beliefs or affiliations;
 - (D) Sexual preferences or behavior; or
 - (E) Beliefs, affiliations, opinions, or lawful activities concerning unions or labor organizations;
- (iv) The examinee may not be subjected to a test when there is sufficient written evidence by a physician that the examinee is suffering from any medical or psychological condition or undergoing any treatment that might cause abnormal responses during the actual testing phase. "Sufficient written evidence" shall constitute, at a minimum, a statement by a physician specifically describing the examinee's medical or psychological condition or treatment and the basis for the physician's opinion that the condition or treatment might result in such abnormal responses.

(2) An employee or prospective employee who exercises the right to terminate the test, or to decline the test for medical reasons with sufficient supporting evidence, shall be subject to adverse employment action only on the same basis as one who refuses to take a

polygraph test, as described in §§ 801.20 and 801.21 of this part.

(c) Any polygraph examination shall consist of one or more pretest phases, actual testing phases, and post-test phases.

(1) *Pretest phase.* The pretest phase consists of the questioning and other preparation of the prospective examinee before the actual use of the polygraph instrument.

(i) During the initial pretest phase, the examinee must be:

(A) Provided with written notice, in a language understood by the examinee, as to when and where the examination will take place and that the examinee has the right to consult with counsel or an employee representative before each phase of the test. Such notice shall be furnished to the examinee at least forty-eight hours, excluding weekend days and holidays, before the time of the examination. The purpose of this requirement is to provide a sufficient opportunity prior to the examination for the examinee to consult with counsel or an employee representative. While an employee has the right to obtain and consult with legal counsel before each phase of the test, the attorney or representative may be excluded from the room where the examination is administered during the actual testing phase.

(B) Informed orally and in writing of the nature and characteristics of the polygraph instrument and examination, including an explanation of the physical operation of the polygraph instrument and the procedure used during the examination.

(C) Provided with a written notice, in a language understood by the examinee, which shall be read to and signed by the examinee. The notice may be in any format (a suggested format is set forth in Appendix A to this part), but must contain at least the following information:

(1)(i) Whether or not the polygraph examination area contains a two-way mirror, a camera, or other device through which the examinee may be observed;

(ii) Whether or not any other device, such as those used in conversation or recording will be used during the examination;

(iii) That both the examinee and the employer have the right, with the other's knowledge, to record electronically the entire examination;

(2)(i) That the examinee has the right to terminate the test at any time;

(ii) That the examinee has the right, and will be given the opportunity, to review all questions to be asked during the test;

(iii) That the examinee may not be asked questions in a manner which degrades, or needlessly intrudes;

(iv) That the examinee may not be asked any questions concerning religious beliefs or opinions; beliefs regarding racial matters; political beliefs or affiliations; matters relating to sexual behavior; beliefs, affiliations, opinions, or lawful activities regarding unions or labor organizations;

(v) That the test may not be conducted if there is sufficient written evidence by a physician that the examinee is suffering from a medical or psychological condition or undergoing treatment that might cause abnormal responses during the examination;

(3)(i) That the test is not and cannot be required as a condition of employment;

(ii) That the employer may not discharge, dismiss, discipline, deny employment or promotion, or otherwise discriminate against the examinee based on the analysis of a polygraph test, or based on the examinee's refusal to take such a test, without additional evidence which would support such action;

(iii)(A) In connection with an ongoing investigation, that the additional evidence required for the employer to take adverse action against the examinee, including termination, may be evidence that the examinee had access to the property that is the subject of the investigation, together with evidence supporting the employer's reasonable suspicion that the examinee was involved in the incident or activity under investigation;

(B) That any statement made by the examinee before or during the test may serve as additional supporting evidence for an adverse employment action, as described in paragraph (c)(1)(i)(C)(3)(ii) of this section, and that any admission of criminal conduct by the examinee may be transmitted to an appropriate government law enforcement agency;

(4) That information acquired from a polygraph test may be disclosed by the examiner or by the employer only:

(i) To the examinee or any other person specifically designated in writing by the examinee to receive such information;

(ii) To the employer that requested the test;

(iii) To a court, governmental agency, arbitrator, or mediator that obtains a court order;

(iv) To a U.S. Department of Labor official when specifically designated in writing by the examinee to receive such information;

(v) By the employer, to an appropriate governmental agency without a court

order where, and only insofar as, the information disclosed is an admission of criminal conduct;

(5) That if any of the examinee's rights or protections under the law are violated, the examinee has the right to file a complaint with the Wage and Hour Division of the U.S. Department of Labor, or to take action in court against the employer. Employers who violate this law are liable to the affected examinee, who may recover such legal or equitable relief as may be appropriate, including employment, reinstatement, and promotion, payment of lost wages and benefits, and reasonable costs, including attorney's fees. The Secretary of Labor may also bring action to restrain violations of the Act, or may assess civil money penalties against the employer.

(6) That the employee's rights under the Act may not be waived, either voluntarily or involuntarily, by contract or otherwise, except as part of a written settlement to a pending action or complaint under the Act, agreed to and signed by the parties.

(ii) During the initial or any subsequent pretest phases, the examinee must be given the opportunity, prior to the actual testing phase, to review all questions in writing that the examiner will ask during each testing phase.

(2) *Actual testing phase.* The actual testing phase refers to that time during which the examiner administers the examination by using a polygraph instrument with respect to the examinee and then analyzes the charts derived from the test. Throughout the actual testing phase, the examiner shall not ask any question that was not presented in writing for review prior to the test. In the case of an ongoing investigation, the examiner shall ensure that all relevant questions pertain to the investigation.

(3) *Post-test phase.* The post-test phase refers to any questioning or other communication with the examinee following the use of the polygraph instrument, including review of the results of the test with the examinee. Before any adverse employment action, the employer must:

(i) Further interview the examinee on the basis of the test results; and

(ii) Give to the examinee a written copy of any opinions or conclusions rendered in response to the test, as well as the questions asked during the test, with the corresponding charted responses.

(4) No testing period shall be less than ninety minutes in length. Such "test period" begins at the time that the examiner begins informing the examinee

of the nature and characteristics of the examination and the instruments involved, as prescribed in section (b)(2)(B) of the Act and § 801.22(e)(1)(i)(B) of this part, and ends when the examiner completes the review of the test results with the examinee. The ninety-minute minimum duration shall not apply if the examinee voluntarily acts to terminate the test.

§ 801.23 Qualifications of and requirements for examiners.

(a) Section 8 (b) and (c) of the Act provides that the limited exemption in section 7(d) of the Act for ongoing investigations, and the security service and controlled substances exemptions in section 7 (e) and (f) of the Act, shall not apply unless the person conducting the polygraph examination meets specified qualifications and requirements.

(b) An examiner must meet the following qualifications:

(1) Have a valid current license, if required by the State in which the test is to be conducted; and

(2) Carry a minimum bond of \$50,000 provided by a surety incorporated under the laws of the United States or of any State, which may under those laws guarantee the fidelity of persons holding positions of trust, or carry an equivalent amount of professional liability coverage.

(c) An examiner must also, with respect to examinees identified by the employer pursuant to § 801.30(c) of this part:

(1) Observe all rights of examinees, as set out in § 801.22 of this part.

(2) Administer no more than five polygraph examinations in any one calendar day, not counting those instances where an examinee voluntarily terminates an examination prior to the actual testing phase, as described in § 801.22(c)(2) of this part.

(3) Administer no polygraph examination which is less than ninety minutes in duration, as described in § 801.22(c)(4) of this part.

(4) Render any opinion or conclusion regarding truthfulness or deception in writing. Such opinion or conclusion must be based solely on the polygraph test results. The written report shall not contain any information other than admissions, information, case facts, and interpretation of the charts relevant to the stated purpose of the polygraph test and shall not include any recommendation concerning the employment of the examinee.

(5) Maintain all opinions, reports, charts, written questions, lists, and other records relating to the test, including statements signed by examinees

advising them of rights under the Act (as described in § 801.22(c)(1)(i)(C) of this part) and any electronic recordings of examinations, for at least three years from the date of the administration of the test. (See § 801.30 of this part for recordkeeping requirements.)

Subpart D—Recordkeeping and Disclosure Requirements

§ 801.30 Records to be preserved for 3 years.

(a) The following records shall be kept for a minimum period of three years from the date of the polygraph examination is conducted (or from the date the examination is requested if no examination is conducted):

(1) Each employer who requests an employee to submit to a polygraph examination in connection with an ongoing investigation involving economic loss or injury shall retain a copy of the statement that sets forth the specific incident or activity under investigation and the basis for testing that particular employee, as required by section 7(d)(4) of the Act and described in § 801.12(a)(4) of this part.

(2) Each employer who administers a polygraph examination under the exemption provided by section 7(f) of the Act (described in § 801.13 of this part) in connection with an ongoing investigation of criminal or other misconduct involving, or potentially involving, loss or injury to the manufacture, distribution or dispensing of a controlled substance, shall retain records specifically identifying the loss or injury in question and the nature of the employee's access to the person or property that is the subject of the investigation.

(3) Each employer shall identify in writing to the examiner persons to be examined pursuant to any of the exemptions under section 7(d), (e) or (f) of the Act (described in § 801.12, 801.13, and 801.14 of this part), and shall retain a copy of such notice.

(4) Each examiner retained to administer examinations to persons identified by employers under paragraph (d) shall maintain all opinions, reports, charts, written questions, lists, and other records relating to polygraph tests of such persons. In addition, the examiner shall maintain records of the number of examinations conducted each day (whether or not conducted pursuant to the Act), and, with regard to tests administered to persons identified by their employer under paragraph (d), the duration of each test period, as defined in § 801.22(c)(4) of this part.

(5) Each employer who retains an examiner to administer examinations

pursuant to any of the exemptions under section 7 (d), (e) or (f) of the Act (described in § 801.12, 801.13, and 801.14 of this part) shall maintain copies of all opinions, reports or other records furnished to the employer by the examiner relating to such examinations.

(b) Each employer shall keep the records required by this Part safe and accessible at the place or places of employment or at one or more established central recordkeeping offices where employment records are customarily maintained. Where the records are maintained at a central recordkeeping office, other than in the place or places of employment, such records shall be made available within 72 hours following notice from the Secretary or an authorized representative.

(c) Each examiner shall keep the records required by this Part safe and accessible at the place or places of business or at one or more established central recordkeeping offices where examination records are customarily maintained. Where the records are maintained at a central recordkeeping office, other than in the place of business, such records shall be made available within 72 hours following notice from the Secretary or an authorized representative.

(d) All records shall be available for inspection and copying by the Secretary or an authorized representative. Information whose disclosure is restricted under section 9 of the Act and § 801.35 of this part shall be made available to the Secretary or the Secretary's representative where the examinee has designated the Secretary, in writing, to receive such information, or by order of a court of competent jurisdiction.

§ 801.35 Disclosure of test information.

Section 9 of the Act prohibits the unauthorized disclosure of any information obtained during a polygraph test by any person, other than the examinee, directly or indirectly, except as follows:

(a) A polygraph examiner or an employer (other than an employer exempt under section 7 (a), (b) or (c) of the Act (described in §§ 800.10 and 801.11 of this part)) may disclose information acquired from a polygraph test only to:

(1) The examinee or an individual specifically designated in writing by the examinee to receive such information;

(2) The employer that requested the polygraph test pursuant to the provisions of this Act;

(3) Any court, governmental agency, arbitrator, or mediator that obtains an order from a court of competent jurisdiction requiring the production of such information;

(4) The Secretary of Labor, or the Secretary's representative, when specifically designated in writing by the examinee to receive such information.

(b) An employer may disclose information from the polygraph test at any time to an appropriate governmental agency without the need of a court order where, and only insofar as, the information disclosed is an admission of criminal conduct.

(c) A polygraph examiner may disclose test charts, without identifying information (but not other examination materials and records) to another examiner(s) for examination and analysis, *provided* that such disclosure is for the sole purpose of consultation and review of the initial examiner's opinion concerning the indications of truthfulness or deception. Such action would not constitute disclosure under this Part provided that the other examiner has no direct or indirect interest in the matter.

Subpart E—Enforcement

§ 801.40 General.

(a) Whenever the Secretary believes that the provisions of the Act or these regulations have been violated, such action shall be taken and such proceedings instituted as deemed appropriate, including the following:

(1) Petitioning any appropriate District Court of the United States for temporary or permanent injunctive relief to restrain violation of the provisions of the Act or this part by any person, and to require compliance with the Act and this part, including such legal or equitable relief incident thereto as may be appropriate, including, but not limited to, employment, reinstatement, promotion, and the payment of lost wages and benefits;

(2) Assessing a civil penalty against any employer who violates any provision of the Act or this part in an amount of not more than \$10,000 for each violation, in accordance with regulations set forth in this part; or

(3) Referring any unpaid civil money penalty which has become a final and unappealable order of the Secretary or a final judgment of a court in favor of the Secretary to the Attorney General for recovery.

(b)(1) Any employer who violates this Act shall be liable to the employee or prospective employee affected by such violation for such legal or equitable relief as may be appropriate, including,

but not limited to, employment, reinstatement, promotion, and the payment of lost wages and benefits.

(2) An action under this subsection may be maintained against the employer in any Federal or State court of competent jurisdiction by an employee or prospective employee for or on behalf of such employee, prospective employee and others similarly situated. Such action must be commenced within a period not to exceed 3 years after the date of the alleged violation. The court, in its discretion, may allow reasonable costs (including attorney's fees) to the prevailing party.

(c) The taking of any one of the actions referred to in paragraph (a) of this section shall not be a bar to the concurrent taking of any other appropriate action.

§ 801.41 Representation of the Secretary.

(a) Except as provided in section 518(a) of Title 28, U.S. Code, relating to litigation before the Supreme Court, the Solicitor of Labor may appear for and represent the Secretary in any civil litigation brought under section 6 of the Act, as described in § 801.40 of this part.

(b) The Solicitor of Labor, through authorized representatives, shall represent the Administrator in all administrative hearings under the provisions of section 6 of the Act and this part.

§ 801.42 Civil money penalties—assessment.

(a) A civil money penalty in an amount not to exceed \$10,000 for any violation may be assessed against any employer for:

(1) Requiring, requesting, suggesting or causing an employee or prospective employee to take a lie detector test or using, accepting, referring to or inquiring about the results of any lie detector test or any employee or prospective employee, other than as provided in the Act of this part;

(2) Taking an adverse action or discriminating in any manner against any employee or prospective employee on the basis of the employee's or prospective employee's refusal to take a lie detector test, other than as provided in the Act or this part;

(3) Discriminating or retaliating against an employee or prospective employee for the exercise of any rights under the Act;

(4) Disclosing information obtained during a polygraph test, except as authorized by the act or this part;

(5) Failing to maintain the records required by the Act or this part;

(6) Resisting, opposing, impeding, intimidating, or interfering with an

official of the Department of Labor during the performance of an investigation, inspection, or other law enforcement function under the Act or this part; or

(7) Violating any other provision of the Act or this part.

(b) In determining the amount of penalty to be assessed for any violation of the Act or this part, the Administrator shall consider the previous record of the employer in terms of compliance with the Act and regulations, the gravity of the violations, and other pertinent factors. The matters which may be considered include, but are not limited to, the following:

(1) Previous history of investigation(s) or violation(s) of the Act or this part;

(2) The number of employees or prospective employees affected by the violation or violations;

(3) The seriousness of the violation or violations;

(4) Efforts made in good faith to comply with the provisions of the Act and this part;

(5) If the violations resulted from the actions or inactions of an examiner, the steps taken by the employer to ensure the examiner complied with the Act and the regulations in this part, and the extent to which the employer could reasonably have foreseen the examiner's actions or inactions;

(6) The explanation of the employer, including whether the violations were the result of a bona fide dispute of doubtful legal certainty;

(7) The extent to which the worker(s) suffered loss or damage;

(8) Commitment to future compliance, taking into account the public interest and whether the person has previously violated the provisions of the Act or this part.

§ 801.43 Civil money penalties—payment and collection.

Where the assessment is directed in a final order of the Department, the amount of the penalty is immediately due and payable to the United States Department of Labor. The person assessed such penalty shall remit promptly the amount thereof as finally determined, to the Administrator by certified check or by money order, made payable to the order of "Wage and Hour Division, Labor". The remittance shall be delivered or mailed to the Wage and Hour Division Regional Office for the area in which the violations occurred.

Subpart F—Administrative Proceedings**General****§ 801.50 Applicability of procedures and rules.**

The procedures and rules contained in this subpart prescribe the administrative process for assessment of civil money penalties for violations of the Act or of these regulations.

Procedures Relating to Hearing**§ 801.51 Written notice of determination required.**

Whenever the Administrator determines to assess a civil money penalty for a violation of the Act or this part, the person against whom such penalty is assessed shall be notified in writing of such determination. Such notice shall be served in person or by certified mail.

§ 801.52 Contents of notice.

The notice required by § 801.51 of this part shall:

- (a) Set forth the determination of the Administrator and the reason or reasons therefore;
- (b) Set forth a description of each violation and the amount assessed for each violation;
- (c) Set forth the right to request a hearing on such determination;
- (d) Inform any affected person or persons that in the absence of a timely request for a hearing, the determination of the Administrator shall become final and unappealable; and
- (e) Set forth the time and method for requesting a hearing, and the procedures relating thereto, as set forth in § 801.53 of this part.

§ 801.53 Request for hearing.

(a) Any person desiring to request an administrative hearing on a civil money penalty assessment pursuant to this part shall make such request in writing to the Administrator of the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, no later than thirty (30) days after the service of the notice referred to in § 801.51 of this part.

(b) No particular form is prescribed for any request for hearing permitted by this subpart. However, any such request shall:

- (1) Be typewritten or legibly written;
- (2) Specify the issue or issues stated in the notice of determination giving rise to such request;
- (3) State the specific reason or reasons why the person requesting the hearing believes such determination is in error;

(4) Be signed by the person making the request or by an authorized representative of such person; and

(5) Include the address at which such person or authorized representative desires to receive further communications relating thereto.

(c) The request for hearing must be received by the Administrator at the address set forth in paragraph (a) of this section, within the time set forth in that paragraph. For the affected person's protection, if the request is by mail, it should be by certified mail, return receipt requested.

Rules of Practice**§ 801.58 General.**

Except as specifically provided in this subpart, and to the extent they do not conflict with the provisions of this subpart, the "Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges" established by the Secretary at 29 CFR Part 18 shall apply to administrative proceedings under this subpart.

§ 801.59 Service and computation of time.

(a) Service of documents under this subpart shall be made by personal service to the individual, officer of a corporation, or attorney of record or by mailing the determination to the last known address of the individual, officer, or attorney. If done by certified mail, service is complete upon mailing. If done by regular mail, service is complete upon receipt by addressee.

(b) Two (2) copies of all pleadings and other documents required for any administrative proceeding provided by this part shall be served on the attorneys for the Department of Labor. One copy shall be served on the Associate Solicitor, Division of Fair Labor Standards, Office of the Solicitor, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, and one copy on the Attorney representing the Department in the proceeding.

(c) Time will be computed beginning with the day following the action and includes the last day of the period unless it is a Saturday, Sunday, or federally-observed holiday, in which case the time period includes the next business day.

§ 801.60 Commencement of proceeding.

Each administrative proceeding permitted under the Act and these regulations shall be commenced upon receipt of a timely request for hearing filed in accordance with § 801.53 of this part.

§ 801.61 Designation of record.

(a) Each administrative proceeding instituted under the Act and this Part shall be identified of record by a number preceded by the year and the letters "EPPA".

(b) The number, letter, and designation assigned to each such proceeding shall be clearly displayed on each pleading, motion, brief, or other formal document filed and docketed of record.

§ 801.62 Caption of proceeding.

(a) Each administrative proceeding instituted under the Act and this part shall be captioned in the name of the person requesting such hearing, and shall be styled as follows:

In Matter of _____,
Respondent.

(b) For the purposes of administrative proceedings under the Act and this part the "Secretary of Labor" shall be identified as plaintiff and the person requesting such hearing shall be named as respondent.

Referral for Hearing**§ 801.63 Referral to Administrative Law Judge.**

(a) Upon receipt of a timely request for a hearing filed pursuant to and in accordance with § 801.53 of this part, the Administrator, by the Associate Solicitor for the Division of Fair Labor Standards or by the Regional Solicitor for the Region in which the action arose, shall by Order of Reference, promptly refer a copy of the notice of administrative determination complained of, and the original or a duplicate copy of the request for hearing signed by the person requesting such hearing or the authorized representative of such person, to the Chief Administrative Law Judge, for a determination in an administrative proceeding as provided herein. The notice of administrative determination and request for hearing shall be filed of record in the Office of the Chief Administrative Law Judge and shall, respectively, be given the effect of a complaint and answer thereto for purposes of the administrative proceeding, subject to any amendment that may be permitted under this part.

(b) A copy of the Order of Reference, together with a copy of this part, shall be served by counsel for the Secretary upon the person requesting the hearing, in the manner provided in 29 CFR 18.3.

§ 801.64 Notice of docketing.

The Chief Administrative Law Judge shall promptly notify the parties of the docketing of each matter.

Procedures Before Administrative Law Judge**§ 801.65 Appearances; representation of the Department of Labor.**

The Associate Solicitor, Division of Fair Labor Standards, or Regional Solicitor shall represent the Department in any proceeding under this part.

§ 801.66 Consent findings and order.

(a) *General.* At any time after the commencement of a proceeding under this part, but prior to the reception of evidence in any such proceeding, a party may move to defer the receipt of any evidence for a reasonable time to permit negotiation of an agreement containing consent findings and an order disposing of the whole or any part of the proceeding. The allowance of such deferment and the duration thereof shall be at the discretion of the Administrative Law Judge, after consideration of the nature of the proceeding, the requirements of the public interest, the representations of the parties, and the probability of an agreement being reached which will result in a just disposition of the issues involved.

(b) *Content.* Any agreement containing consent findings and an order disposing of a proceeding or any part thereof shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the notice of administrative determination (or amended notice, if one is filed), and the agreement;

(3) A waiver of any further procedural steps before the Administrative Law Judge; and

(4) A waiver of any right to challenge or contest the validity of the findings and order entered into, in accordance with the agreement.

(c) *Submission.* On or before the expiration of the time granted for negotiations, the parties or their authorized representatives or their counsel may:

(1) Submit the proposed agreement for consideration by the Administrative Law Judge; or

(2) Inform the Administrative Law Judge that agreement cannot be reached.

(d) *Disposition.* In the event an agreement containing consent findings and an order is submitted within the time allowed therefor, the Administrative Law Judge, within thirty

(30) days thereafter, shall, if satisfied with its form and substance, accept such agreement by issuing a decision based upon the agreed findings.

§ 801.67 Decision and Order of Administrative Law Judge.

(a) The Administrative Law Judge shall prepare, as promptly as practicable after the expiration of the time set for filing proposed findings and related papers, a decision on the issues referred by the Secretary.

(b) The decision of the Administrative Law Judge shall be limited to a determination whether the respondent has violated the Act or these regulations and the appropriateness of the remedy or remedies imposed by the Secretary. The Administrative Law Judge shall not render determinations on the legality of a regulatory provision or the constitutionality of a statutory provision.

(c) The decision of the Administrative Law Judge, for purposes of the Equal Access to Justice Act (5 U.S.C. 504), shall be limited to determinations of attorney fees and/or other litigation expenses in adversary proceedings requested pursuant to § 801.53 of this part which involve the imposition of a civil money penalty assessed for a violation of the Act or this Part.

(d) The decision of the Administrative Law Judge shall include a statement of findings and conclusions, with reasons and basis therefor, upon each material issue presented on the record. The decision shall also include an appropriate order which may be to affirm, deny, reverse, or modify, in whole or in part, the determination of the Secretary. The reason or reasons for such order shall be stated in the decision.

(e) The Administrative Law Judge shall serve copies of the decision on each of the parties.

(f) If any party desires review of the decision of the Administrative Law Judge, a petition for issuance of a Notice of Intent shall be filed in accordance with § 801.69 of this subpart.

(g) The decision of the Administrative Law Judge shall constitute the final order of the Secretary unless the Secretary, pursuant to § 801.70 of this subpart issues a Notice of Intent to Modify or Vacate the Decision and Order.

Modification or Vacation of Decision and Order of Administrative Law Judge**§ 801.68 Authority of the Secretary.**

The Secretary may modify or vacate the Decision and Order of the Administrative Law Judge whenever the

Secretary concludes that the Decision and Order:

(a) Is inconsistent with a policy or precedent established by the Department of Labor;

(b) Encompasses determinations not within the scope of the authority of the Administrative Law Judge;

(c) Awards attorney fees and/or other litigation expenses pursuant to the Equal Access to Justice Act which are unjustified or excessive; or

(d) Otherwise warrants modifying or vacating.

§ 801.69 Procedures for initiating review.

(a) Within twenty (20) days after the date of the decision of the Administrative Law Judge, the respondent, the Administrator, or any other party desiring review thereof, may file with the Secretary an original and two copies of a petition for issuance of a Notice of Intent as described under § 801.70. The petition shall be in writing and shall contain a concise and plain statement specifying the grounds on which review is sought. A copy of the Decision and Order of the Administrative Law Judge shall be attached to the petition.

(b) Copies of the petition shall be served upon all parties to the proceeding and on the Chief Administrative Law Judge.

§ 801.70 Implementation by the Secretary.

(a) Whenever, on the Secretary's own motion or upon acceptance of a party's petition, the Secretary believes that a Decision and Order may warrant modifying or vacating, the Secretary shall issue a Notice of Intent to modify or vacate the Decision and Order in question.

(b) The Notice of Intent to Modify or Vacate a Decision and Order shall specify the issue or issues to be considered, the form in which submission shall be made (i.e., briefs, oral argument, etc.), and the time within which such presentation shall be submitted. The Secretary shall closely limit the time within which the briefs must be filed or oral presentations made, so as to avoid unreasonable delay.

(c) The Notice of Intent shall be issued within thirty (30) days after the date of the Decision and Order in question.

(d) Service of the Notice of Intent shall be made upon each party to the proceeding, and upon the Chief Administrative Law Judge, in person or by certified mail.

§ 801.71 Filing and service.

(a) *Filing.* All documents submitted to the Secretary shall be filed with the Secretary of Labor, U.S. Department of Labor, Washington, DC 20210.

(b) *Number of copies.* An original and two copies of all documents shall be filed.

(c) *Computation of time for delivery by mail.* Documents are not deemed filed with the Secretary until actually received by the Secretary. All documents, including documents filed by mail, must be received by the Secretary either on or before the due date. No additional time shall be added where service of a document requiring action within a prescribed time thereafter, was made by mail.

(d) *Manner and proof of service.* A copy of all documents filed with the Secretary shall be served upon all other parties involved in the proceeding. Service under this section shall be by personal delivery or by mail. Service by mail is deemed effected at the time of mailing to the last known address.

§ 801.72 Responsibility of the Office of Administrative Law Judges.

Upon receipt of the Secretary's Notice of Intent to Modify or Vacate the Decision and Order of an Administrative Law Judge, the Chief Administrative Law Judge shall, within (15) days, fifteen forward a copy of the complete hearing record to the Secretary.

§ 801.73 Final decision of the Secretary.

The Secretary's final Decision and Order shall be served upon all parties and the Chief Administrative Law Judge, in person or by certified mail.

Record**§ 801.74 Retention of official record.**

The official record of every completed administrative hearing provided by this part shall be maintained and filed under the custody and control of the Chief Administrative Law Judge.

§ 801.75 Certification of official record.

Upon receipt of timely notice of appeal to a United States District Court

of a Decision and Order issued under this part, the Chief Administrative Law Judge shall promptly certify and file with the appropriate United States District Court, a full, true, and correct copy of the entire record, including the transcript of proceedings.

Appendix A—Notice to Examinee

Section 8(b) of the Employee Polygraph Protection Act, and Department of Labor regulations (29 CFR 801.22) require that you be given the following information before taking a polygraph examination:

1. (a) The polygraph examination area [does] [does not] contain a two-way mirror, a camera, or other device through which you may be observed.

(b) Another device, such as those used in conversation or recording, [will] [will not] be used during the examination.

(c) Both you and the employer have the right, with the other's knowledge, to record electronically the entire examination.

2. (a) You have the right to terminate the test at any time.

(b) You have the right, and will be given the opportunity, to review all questions to be asked during the test.

(c) You may not be asked questions in a manner which degrades, or needlessly intrudes.

(d) You may not be asked any questions concerning: Religious beliefs or opinions; beliefs regarding racial matters; political beliefs or affiliations; matters relating to sexual behavior; beliefs, affiliations, opinions, or lawful activities regarding unions or labor organizations.

(e) The test may not be conducted if there is sufficient written evidence by a physician that you are suffering from a medical or psychological condition or undergoing treatment that might cause abnormal responses during the examination.

3. (a) The test is not and cannot be required as a condition of employment.

(b) The employer may not discharge, dismiss discipline, deny employment or promotion, or otherwise discriminate against you based on the analysis of a polygraph test, or based on your refusal to take such a test without additional evidence which would support such action.

(c)(1) In connection with an ongoing investigation, the additional evidence required for an employer to take adverse action against you, including termination, may be (A) evidence that you had access to the property that is the subject of the investigation, together with (B) the evidence

supporting the employer's reasonable suspicion that you were involved in the incident or activity under investigation.

(2) Any statement made by you before or during the test may serve as additional supporting evidence for an adverse employment action, as described in 3(b) above, and any admission of criminal conduct by you may be transmitted to an appropriate government law enforcement agency.

4. (a) Information acquired from a polygraph test may be disclosed by the examiner or by the employer only:

(1) To you or any other person specifically designated in writing by you to receive such information;

(2) To the employer that requested the test;

(3) To a court, governmental agency, arbitrator, or mediator that obtains a court order;

(4) To a U.S. Department of Labor official when specifically designated in writing by you to receive such information.

(b) Information acquired from a polygraph test may be disclosed by the employer to an appropriate governmental agency without a court order where, and only insofar as, the information disclosed is an admission of criminal conduct.

5. If any of your rights or protections under the law are violated, you have the right to file a complaint with the Wage and Hour Division of the U.S. Department of Labor, or to take action in court against the employer. Employers who violate this law are liable to the affected examinee, who may recover such legal or equitable relief as may be appropriate, including employment, reinstatement, and promotion, payment of lost wages and benefits, and reasonable costs, including attorney's fees. The Secretary of Labor may also bring action to restrain violations of the Act, or may assess civil money penalties against the employer.

6. Your rights under the Act may not be waived, either voluntarily or involuntarily, by contract or otherwise, except as part of a written settlement to a pending action or complaint under the Act, and agreed to and signed by the parties.

I acknowledge that I have received a copy of the above notice, and that it has been read to me.

(Date)

(Signature)

[FR Doc. 88-24377 Filed 10-20-88; 8:45 am]

BILLING CODE 4510-27-M

Federal Register

Friday
October 21, 1988

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 71

Proposed Alteration of Airport Radar Service Area; Metropolitan Oakland International, CA; Notice of Proposed Rulemaking

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-AWA-54]

Proposed Alteration of Airport Radar Service Area; Metropolitan Oakland International, CA**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Metropolitan Oakland International Airport, CA, Airport Radar Service Area (ARSA). This proposal would adjust the lateral limits of the ARSA to remove the airspace that is within the outer core of the ARSA, north of Interstate 580, from regulatory status.

DATES: Comments must be received on or before December 23, 1988.

ADDRESSES: Send comments on the proposal in triplicate to: Director, FAA, Western-Pacific Region, Attention: Manager, Air Traffic Division, Docket No. 87-AWA-54, Federal Aviation Administration, P.O. Box 92007, Worldway Postal Center, Los Angeles, CA 90009.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Betty Harrison, Airspace Branch (ATO-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC. 20591; telephone: (202) 267-9254.

SUPPLEMENTARY INFORMATION:
Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above.

Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 87-AWA-54." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3484.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to modify the Metropolitan Oakland International ARSA as follows:

Eliminate the area within the outer core, north of Interstate 580. Interstate 580 is a well-known, easily recognizable landmark for visual flight rules (VFR) aircraft. During user forums and feedback sessions following the original implementation of this ARSA, substantial comments were received supporting the exclusion of this area so that the heavily used VFR route, north of Interstate 580, would not be compressed below 2,100 feet MSL. Interstate 580 is located north of the final approach courses of the standard instrument approach procedures for Oakland Airport's Runway 27; thus, the final approach courses would still be protected by the remainder of the outer core. More airspace outside the ARSA would be available in the Lake Chabot area, which would reduce aircraft congestion and provide users more freedom without adversely affecting the

Oakland ARSA. Environmentally, aircraft noise could be reduced by allowing nonparticipating aircraft to cross Castro Valley at higher altitudes.

For the reasons discussed under "Regulatory Evaluation," the FAA has determined that this proposed regulation is not a "major rule" under Executive Order 12291 and is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

Regulatory Evaluation Summary

The following is a summary of the cost impact and benefit assessment of an NPRM to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71). A more detailed regulatory evaluation has been placed in the docket (87-AWA-54).

Summary of Costs

The FAA estimates the costs associated with the NPRM to be very minimal. The rationale for this determination is based upon two factors:

1. Cost evaluation for the final rule (ASD 85-AW-4, 51 FR 8284, March 10, 1986, "Establishment of Airport Radar Service Areas") determined potential costs would not materialize to any appreciable degree, and if they did occur, such costs would be transitional, relatively low in magnitude, or attributable to specific implementation problems that have been experienced at a very small minority of ARSA sites.

2. Since the NPRM seeks to restore airport radar service area airspace to airport traffic area airspace, there should be little or no cost to the aviation public. Furthermore, since the rule would reduce congestion in the affected airspace and allow the final approach course to Metropolitan Oakland International's Runway 27 to remain protected, sectional charts would be updated during the regular chart cycle.

Summary of Benefits

Many of the benefits of the modification are not quantifiable. The FAA expects the benefits of this proposal will accrue in terms of efficiency and environmental factors. First, controllers would have less airspace to monitor thereby enabling them to concentrate more fully on targets in and around the Metropolitan Oakland International traffic patterns. Second, increased airspace in the Lake Chabot area outside the ARSA would reduce congestion and provide users with more freedom without adversely affecting the Oakland ARSA or posing a safety threat. Finally, aircraft noise would be reduced considerably by

allowing nonparticipating pilots to cross Castro Valley at a higher altitude.

Conclusion

On balance, the FAA believes that the restoration of the airspace would benefit various users at a near zero cost and expects that the establishment of this proposal would produce long term, ongoing benefits far in excess of any costs which may be incurred.

Regulatory Flexibility Determination

The proposal to eliminate the ARSA area north of Interstate 580 would release ARSA controlled airspace not required for safety reasons. The establishment of this proposed rule would, in effect, lessen government regulation in the affected areas; thus, it would not pose an economic burden upon independently owned and operated small businesses and small not-for-profit organization.

Trade Impact Statement

The proposed regulation would only impact the Metropolitan Oakland International ARSA. As such, it would have no effect on the sale of foreign aviation products or services in the United States, nor would it affect the sale of American products or services in foreign countries.

Federalism Implications

The regulation proposed herein would

not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12616 it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed under "Regulatory Evaluation Summary," the FAA certifies that the proposed regulation, if adopted, will not result in a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Airport radar service areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) [Revised Pub. L. 97-449, January 12, 1983]; 14 CFR 11.69.

§ 71.50 [Amended]

2. § 71.501 is amended as follows:

Metropolitan Oakland International Airport, CA [Revised]

That airspace extending upward from the surface to and including 4,000 feet MSL within a 5-mile radius of the Metropolitan Oakland International Airport (1st. 37°43'17"N., long. 122°13'11"W.), excluding that airspace contained within the San Francisco, CA, Terminal Control Area (TCA); and that airspace extending upward from 1,500 feet MSL to and including 4,000 feet MSL within a 10-mile radius of the Metropolitan Oakland International Airport, excluding that airspace contained within the San Francisco TCA, and that airspace beyond a 5-mile radius from the Metropolitan Oakland International Airport from the Oakland VORTAC 004° radial clockwise to the northern edge of U.S. Interstate 580, and that airspace beyond the 15-mile radius of the San Francisco TCA.

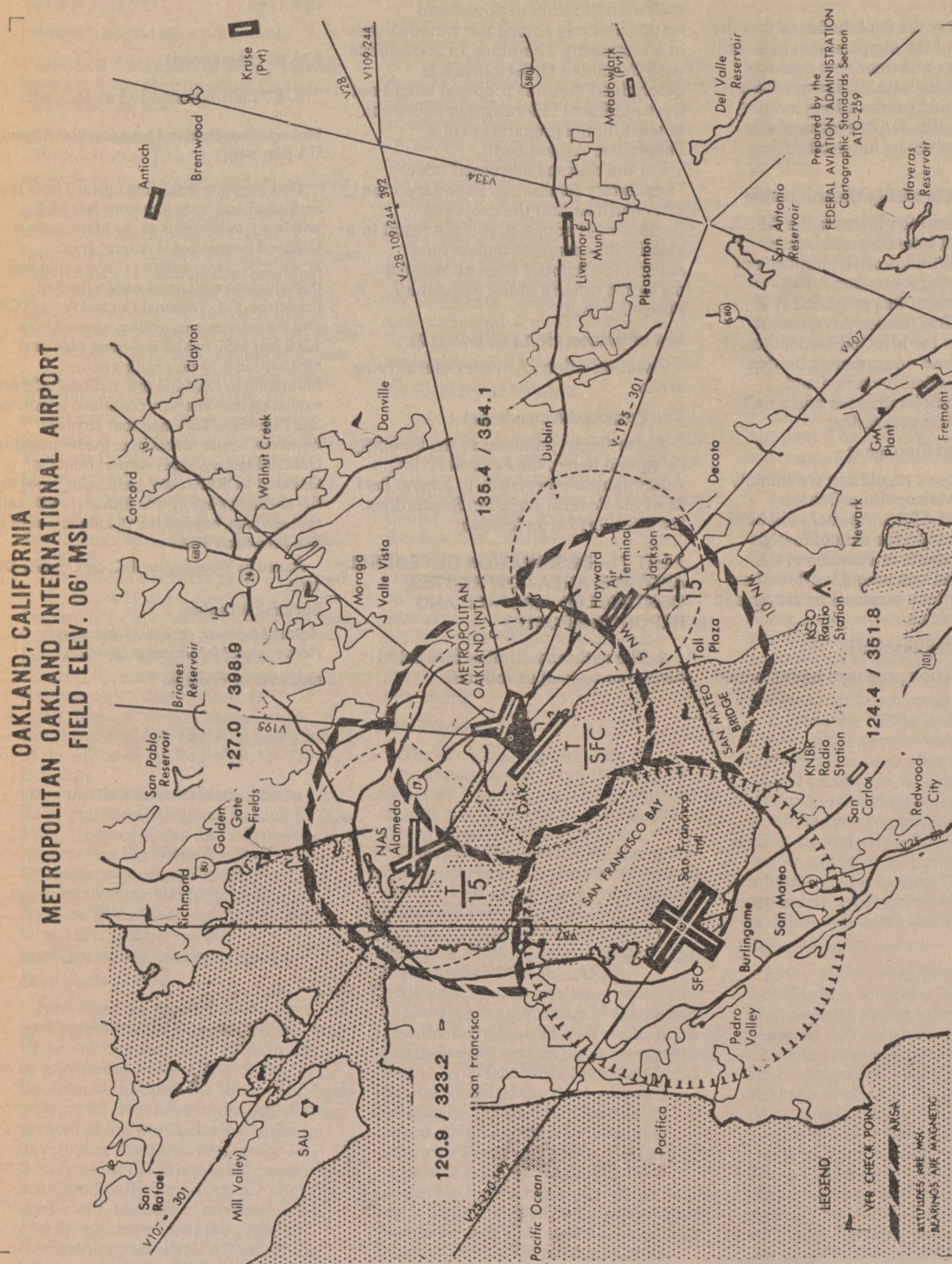
Issued in Washington, DC, on October 17, 1988.

Shelomo Wugalter,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

BILLING CODE 4910-13-M

(NOT TO BE USED FOR NAVIGATION)



[FR Doc. 88-24422 Filed 10-20-88; 8:45 am]

BILLING CODE 4910-13-C

Test Report Federal Register

Friday
October 21, 1988

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 312 and 314

Investigational New Drug, Antibiotic and
Biological Drug Product Regulations;
Procedures for Drugs Intended To Treat
Life-Threatening and Severely Debilitating
Illnesses; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. 88N-0359]

Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended To Treat Life-Threatening and Severely Debilitating Illnesses

AGENCY: Food and Drug Administration.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing interim regulatory procedures designed to speed the availability of new therapies to desperately ill patients, while preserving appropriate guarantees for safety and effectiveness. These procedures are intended to facilitate the development, evaluation, and marketing of such products, especially where no satisfactory alternative therapies exist. These procedures reflect the recognition that physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious illnesses. These procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated. The procedures apply to products intended to treat acquired immunodeficiency syndrome (AIDS), some cancers, and other life-threatening or severely-debilitating illnesses. FDA is issuing these procedures as an interim rule with opportunity for public comment.

DATES: Interim rule effective October 21, 1988; comments by December 20, 1988.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305) Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Steven H. Unger, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049,

or

Steven F. Falter, Center for Biologics Evaluation and Research (HFB-130), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-295-8046.

SUPPLEMENTARY INFORMATION:

Expediting the availability of promising new therapies has been a major priority of FDA over the past several years. In the Federal Register of May 22, 1987 (52 FR 19466), FDA issued new regulations designed to increase the availability to desperately ill patients of promising investigational new drug (IND) and biological products before general marketing begins. This rulemaking initiative, known as the treatment IND program, was endorsed by the President's Task Force on Regulatory Relief, chaired by Vice President George Bush. The final rule has received broad support from the medical and patient communities. The significance and utility of the treatment IND program has also been recognized and endorsed by the President's Commission on the Human Immunodeficiency Virus (HIV) Epidemic.

The treatment IND regulations became effective on June 22, 1987. Since that time, seven promising experimental therapies have been made available to patients stricken with AIDS, cancer, Parkinson's disease, and other serious conditions. In February 1988, the American Medical Association and FDA cosponsored a major national conference intended to educate physicians and health care organizations about the treatment IND program. FDA has also publicized specific treatment IND approval actions in both medical and lay journals (Refs. 1 through 8).

The treatment IND program is part of FDA's comprehensive efforts to facilitate the development and availability of significant new therapies. For example, through its implementation of the Orphan Drug Act, enacted in 1983, FDA has given special emphasis to potential new therapies for rare diseases or conditions. Since 1983, FDA has granted orphan drug designation to over 200 products, many of which are for life-threatening illnesses. (Orphan drug designation provides the commercial sponsor with certain economic incentives to encourage drug development, including tax credits for the cost of clinical development and exclusive marketing rights for the designated indication upon marketing approval.) FDA has approved for marketing 27 such orphan products, including therapies to treat such life-threatening illnesses as leukemia and AIDS.

FDA has also instituted a number of management improvements designed to expedite the evaluation of AIDS-related products in particular. These include establishment of a top "1-AA" priority for the review of all AIDS products, and

the creation of two new divisions—one for drugs and one for biologicals—to give special focus to the review of such products. FDA's actions have led to the approval in record time of the first drug, zidovudine (formerly called AZT), to treat the AIDS virus, as well as approval for human testing of the first potential AIDS vaccines.

Building on these achievements, on August 3, 1988, Vice President Bush, in his capacity as chairman of the Presidential Task Force on Regulatory Relief, requested FDA to develop procedures for expediting the marketing of new therapies intended to treat AIDS and other life-threatening illnesses. This charge recognized the urgency felt by desperately ill patients and their families. The charge was directed to FDA as the Federal agency that regulates the transfer of the fruits of biomedical research to the marketplace.

The procedures contained in this notice respond to the Vice President's charge. In developing these procedures, FDA met informally with representatives of AIDS interest groups as well as with representatives of consumer, health professional, academic, orphan drug, and industry organizations. FDA also met informally with leadership of the National Institutes of Health.

As described further below, FDA is issuing these new procedures as an interim rule, effective immediately, with an opportunity for public comment. Highlights of the interim rule are summarized below, followed by a section-by-section description of the new procedures.

I. Highlights of the Regulations

New procedures are being codified as part of FDA's IND regulations, by adding a new Subpart E consisting of §§ 312.80 through 312.88, and by adding a conforming amendment to FDA's new drug application (NDA) regulations, new paragraph (c) of § 314.25. The purpose of these new procedures (§ 312.80) is to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening or severely-debilitating illnesses, especially where no satisfactory alternative therapies exist. The procedures themselves focus on the entire drug development and evaluation process—from early preclinical and clinical testing, through FDA evaluation of controlled clinical trials and marketing applications, to postmarketing surveillance—in order to treat the entire process as a coherent whole and thereby significantly increase its overall efficiency.

The scope of the new procedures (§ 312.81) will apply to new drugs, antibiotics, and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely-debilitating illnesses. Within the context of these procedures, the term "life-threatening" is defined to include diseases where the likelihood of death is high unless the course of the disease is interrupted (e.g., AIDS and cancer), as well as diseases or conditions with potentially fatal outcomes where the end point of clinical trial analysis is survival (e.g., increased survival in persons who have had a stroke or heart attack). The term "severely-debilitating" refers to diseases or conditions that cause major irreversible morbidity (e.g., blindness or neurological degeneration).

A key component of the procedures is early consultation between FDA and drug sponsors (§ 312.82) to seek agreement on the design of necessary preclinical and clinical studies needed to gain marketing approval. Such consultation is intended to improve the efficiency of the process by preventing false starts and wasted effort that could otherwise result from studies that are flawed in design. Most important, at the end of early (phase 1) clinical testing, FDA and the sponsor will seek to reach agreement on the proper design of phase 2 controlled clinical trials, with the goal that such research will be adequate to provide sufficient data on the product's safety and effectiveness to support a decision on its approvability for marketing. Where appropriate, FDA will invite to such meetings one or more outside expert scientific consultants or advisory committee members.

If the preliminary analysis of test results appears promising, FDA may ask the sponsor (§ 312.83) to submit a treatment protocol to be reviewed under the treatment IND regulations. Such a treatment protocol, if submitted and granted, would serve as a bridge between the completion of early stages of clinical trials and final marketing approval.

Once phase 2 testing and analysis is completed by the sponsor and a marketing application is submitted, FDA will evaluate the data utilizing a medical risk-benefit analysis (§ 312.84). As part of this evaluation, FDA will consider whether the benefits of the drug outweigh the known and potential risks of the drug and the need to answer remaining questions about risks and benefits of the drug, taking into consideration the severity of the disease and the absence of satisfactory alternative therapy. In making decisions on whether to grant marketing approval

for products that have been the subject of an end-of-phase 1 meeting under this rule, FDA will usually seek the advice of outside expert scientific consultants or advisory committees.

As a conforming amendment, a new paragraph (c) is being added to § 314.125 of FDA's NDA regulations. This paragraph is designed to make clear that FDA's evaluation of marketing applications for drugs to treat life-threatening and severely-debilitating diseases will incorporate the criteria being added to § 312.84. These criteria include the adoption of a medical risk-benefit analysis when assessing the safety and effectiveness of these drugs.

Finally, when approval or licensing of a product is being granted, FDA may seek agreement from the sponsor (§ 312.85) to conduct certain postmarketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in phase 2 studies, use of the drug in other patient populations or other stages of the disease, and use of the drug over a longer period of time.

These procedures are modeled after the highly successful development, evaluation, and approval of zidovudine, the first drug approved to treat the AIDS virus. Close consultation between FDA, the sponsor, and the National Institutes of Health resulted in efficient preclinical animal testing (2 to 4 weeks in duration), focused phase 1 clinical testing, and a well-designed and conducted multicenter phase 2 clinical trial that provided dramatic evidence of increased survival in patients with advanced cases of AIDS. Given such evidence, FDA approved a treatment protocol in 5 days, and marketing approval in 107 days. Concurrent with approval, the sponsor agreed to conduct phase 4 research studying the effects of zidovudine in patients at an earlier stage of the disease. In total, the drug development and evaluation process, which takes an average of 8 years from initial human testing under an IND to final marketing approval, took only 2 years for zidovudine. Although the total development time will vary with different drugs, FDA believes that the approach contained in these new procedures has great potential for increasing significantly the efficiency of the drug development and evaluation process for the drugs affected.

Moreover, to the extent that the Commissioner determines that clinical trials to treat life-threatening or

severely-debilitating diseases are already underway and are consistent with the requirements of these rules, upon his own initiative and in cooperation with the drug sponsor, he may recommend that a marketing application be submitted under the new procedures.

In conjunction with these procedures, FDA may, in certain circumstances, undertake focused regulatory research (§ 312.86) addressing critical rate-limiting aspects of the preclinical, chemical/manufacturing, and clinical phases of drug development and evaluation. The FDA Commissioner and other agency officials will also actively monitor (§ 312.87) the progress of the conduct and evaluation of clinical trials for products covered by these procedures, and will be involved in facilitating their appropriate progress.

The final provision of these procedures (§ 312.88) references applicable safeguards inherent in existing FDA regulations to ensure patient safety during clinical testing and the safety of products following marketing approval. These safeguards include FDA requirements regarding informed consent and institutional review boards. These safeguards further include the review of animal studies prior to initial human testing, and the monitoring of adverse drug experiences during the IND, marketing application, and postmarketing phases.

FDA believes that this program, taken as a whole, establishes a new and innovative approach to stimulating the development of particularly important drugs, while at the same time building on past practices that have proven to be successful.

II. Effective Date and Opportunity for Public Comment

For the reasons described below, FDA is issuing these procedures as an interim rule, with an opportunity for public comment. Because of the urgency associated with life-threatening illnesses, the agency intends to begin implementation of these procedures immediately, but will consider modifications to them based on issues raised during the comment period and experience gained under the interim rule.

The program established in this interim rule is intended to bring about a significant improvement in the efficiency of the development, evaluation, and marketing of new therapies for life-threatening and severely-debilitating illnesses, while preserving appropriate guarantees for safety and effectiveness. Although the program is important, it

builds upon managerial and regulatory options available under existing practices and procedures. The opportunity for early consultation with sponsors on the design of clinical trials, for example, is permissible under the existing investigational new drug review provisions of FDA's regulations. Because the new program represents a fundamental commitment to expediting the development of innovative products, it is appropriate to identify and describe the components of that program and to codify them for ready reference by affected persons. Moreover, the amendment to Part 314, requiring consideration of risk-benefit criteria in decisions to approve or disapprove these drugs, is consistent with the flexibility granted to the Agency under the statute in determining whether substantial evidence of safety and effectiveness has been demonstrated.

To the extent that the elements of the program announced today are regarded as new rules, they are within the exception to the Administrative Procedure Act notice-and-comment requirement for general statements of policy and rules of agency organization, procedure, and practice (5 U.S.C. 553(b)(A)). Moreover, if the new program is regarded as substantive rulemaking, the Commissioner hereby finds good cause for not providing notice and an opportunity to comment prior to its effectiveness. The importance of developing new therapies for life-threatening diseases has been highlighted in recent years by the AIDS crisis. In addition, the sustained search by drug researchers for treatments for many other diseases, including Alzheimer's disease and cancer, merits immediate attention. FDA believes that, as promising new therapies for these diseases are identified, they must be developed by sponsors and evaluated by the agency as expeditiously as possible. It would therefore be contrary to the public interest to delay the implementation of this program pending the time necessary to engage in the APA's notice-and-comment procedures, and such delay would also be unnecessary because the program derives from existing regulations that have already been the subject of notice and an opportunity for comment (5 U.S.C. 553(b)(B); 21 CFR 10.40(e)).

FDA believes, however, that it should invite and consider public comment on its practices and procedures for reviewing investigational new drug, new drug approval, and biologics license applications, including those described in this notice.

III. Contents of the Program

A. Purpose

The drug development process is generally thought of, in simplified terms, as consisting of three phases of human testing to determine if a drug is safe and effective: Phase 1 with 10 to 50 patients to study how the drug is tolerated, metabolized, and excreted; phase 2 with 50 to 200 patients in which the safety and efficacy of the drug are first evaluated in controlled trials; and phase 3 with 200 to 1,000 or more patients to confirm and expand upon the safety and efficacy data obtained from the first two phases. (For purposes of this discussion, the word "drug" is meant to include new drugs, antibiotic drugs, and biological products.)

A recent study of new drug development has documented the percentage of drugs whose development is discontinued after each of these phases. Of the 174 new chemical entities that entered phase 1 testing under U.S. IND's between 1976 and 1978, 70 percent successfully completed phase 1 and moved on to phase 2, while 33 percent successfully completed phase 2 and moved on to phase 3. At this point the dropout rate slowed considerably, as 27 percent successfully completed phase 3 and were submitted to FDA in the form of a marketing application, and 20 percent actually received marketing approval from the agency (Ref. 9).

The three phases describe the usual process of drug development, but they are not statutory requirements. The basis for marketing approval is the adequacy of the data available; progression through the particular phases is simply the usual means the sponsor uses to collect the data needed for approval. The statute itself focuses on the standard of evidence needed for approval, as derived from adequate and well-controlled clinical investigations, with no mention of phases 1, 2, and 3. FDA believes that if sufficient attention is paid to the quality and amount of data obtained in phase 2, it should be possible to identify early those drugs that represent safe and effective treatments for life-threatening and severely-debilitating diseases—and to develop the evidence needed for their marketing—in the course of carrying out the first controlled trials.

This program is based on that premise. For drugs intended to treat life-threatening and severely debilitating illnesses, it should be possible to reduce the total premarket drug development time by designing and conducting phase 2 controlled trials that are capable of providing necessary data on the drug's safety and effectiveness. FDA would

analyze data from such studies utilizing medical risk-benefit considerations appropriate for drugs intended to treat life-threatening or severely-debilitating illnesses. The treatment IND, as appropriate, could continue to serve as a bridge between phase 2 trials and the point of marketing approval. Drug sponsors might also conduct postmarketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. The FDA Commissioner and other agency officials would actively monitor the process to ensure that such products are developed by the sponsor and analyzed by the agency as expeditiously as possible.

Section 312.80 of the rule summarizes the program's purpose: to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening or severely-debilitating illnesses, especially where no satisfactory alternative therapy exists. As stated in FDA's new drug application regulations (§ 314.105(c)), while the statutory standards of safety and effectiveness apply to all drugs, the many kinds of drugs that are subject to them, and the wide range of uses for those drugs, demand flexibility in applying the standards. In promulgating this interim rule, FDA has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness. The procedures contained in this rule reflect the recognition that physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious illnesses. These procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated. The procedures outlined in this notice should be interpreted consistent with this statement of purpose.

B. Scope

Section 312.81 of the rule outlines the scope of this rule. The rule applies to new drug, antibiotic, and biological products being studied for their safety and effectiveness in treating life-threatening or severely-debilitating diseases.

A "life-threatening" disease is defined as one in which the likelihood of death is high unless the course of the disease is interrupted (e.g., progression from asymptomatic HIV infection to

symptomatic HIV infection, or further progression to a later stage of AIDS; metastatic cancer; amyotrophic lateral sclerosis). This use of the term "life-threatening" plainly includes any disease whose progression is likely to lead to death, especially in a short period of time (e.g., 6 months to 1 year). This section also applies to any condition in which a study is to be carried out to determine whether the treatment has a beneficial effect on survival (e.g., increased survival after a stroke or heart attack).

The term "severely-debilitating" is defined as a disease or condition that leads to major irreversible morbidity (e.g., severe functional deficits in multiple sclerosis, Alzheimer's disease or progressive ankylosing spondylitis; prevention of blindness due to cytomegalovirus infection in AIDS patients).

With respect to "severely-debilitating" illnesses, the procedures contained in this rule are applicable to those instances where the studies proposed will examine the treatment's capacity to prevent or reverse what would otherwise be irreversible damage, such as putting ankylosing spondylitis into remission and stopping joint damage and deformity, or preventing blindness. It is in such studies that excellence in study design and an early answer to key questions on safety and effectiveness are especially critical. The agency notes that there are many other studies that examine symptomatic relief (e.g., pain of ankylosing spondylitis) rather than irreversible morbidity. While products being studied for symptomatic relief of a serious disease would likely qualify for treatment IND consideration under § 312.34(b)(2), they would not be covered by the procedures contained in this interim rule.

In all of the cases covered by these new procedures, when the end points of clinical study relate to survival or prevention of major disability, they are of such great importance that it is imperative that the first controlled clinical trials be designed and conducted as well as possible. If this is not done, preliminary reports of success from poorly designed studies might make it difficult ever to carry out the proper trials. FDA believes it is clearly in the public interest to assure in such situations, to the extent possible, that the first clinical trials be designed so that the true merit of the drug or biologic can be evaluated as promptly as possible. FDA will also expedite the designation of eligible orphan products to provide additional incentive for their development.

The agency recognizes that the scope of these procedures is subject to interpretation, and the examples given above are illustrative only. FDA intends to be flexible in its implementation of this program and, subject to available resources, provide early advice when it is sought. The agency encourages sponsors to consult with FDA on the program's applicability to particular products.

C. Elements of the Program

1. Early consultation. A key component to be addressed is early consultation, which is covered in § 312.82 of the rule. In 1987, FDA codified the practice that, upon request of a drug's sponsor, FDA medical staff will hold a conference with the sponsor at the end of phase 2 testing. (See § 312.47(b)(1).) The goal of this conference is to reach agreement on a plan of phase 3 testing that will provide the needed remaining evidence of the drug's safety and efficacy to gain marketing approval. If, however, the evidence obtained from well-planned and well-executed phase 2 research is sufficient under the statute for marketing approval, there may be no need for additional phase 3 premarket testing, and the drug can become available much more rapidly than usual.

This is most likely to occur for drugs to treat life-threatening illnesses where the relatively small amount of data available at this stage may nevertheless be sufficient for approval. For example, phase 2 research was sufficient for approval of zidovudine the only drug approved thus far to treat the AIDS virus. Zidovudine was developed and approved in record time, largely because further premarketing (phase 3) studies were not needed to support safety and effectiveness following completion of a highly successful well-controlled multicenter phase 2 study that demonstrated dramatic effects on survival.

There have been other circumstances, particularly in the oncology area, where early (phase 2) results were such that additional studies were not needed to conclude that the drug was effective and that its benefits outweighed its risks. For example, the licensing of alpha interferons to treat hairy cell leukemia was based on phase 2 trials that showed partial or complete remission of the disease in 75 to 90 percent of patients.

To build upon these successes, FDA is instituting a process for conferences to be held at the end of phase 1 (rather than waiting until the end of phase 2) with the sponsors of drugs and biologics intended to treat life-threatening and severely-debilitating illnesses, especially where there are no

satisfactory alternative therapies. The purpose of these conferences will be to review the product's phase 1 test results and phase 2 plans for clinical testing. If enough is known about the drug at that time, agreement would be reached on a phase 2 testing program (e.g., the design of the studies, the number of patients to be tested, the end points to be used, and the proposed mode of replication), that would be sufficient to establish the drug's safety and effectiveness. Where the data resulting from these phase 2 studies prove sufficient to allow a determination that, on the basis of risk-benefit considerations detailed further below, the drug is safe and effective, FDA will approve the drug without further preapproval studies. In this case, phase 2 thus obviates the need for further research in phase 3, if the phase 2 trials prove successful. Of course, when the results of phase 2 research do not provide evidence that fulfills the statutory criteria for approval, further preapproval studies will be necessary.

Because the end-of-phase 1 conference serves the same function (except earlier in the process) as an end-of-phase 2 conference would otherwise serve, FDA will apply the same procedures to both meetings, as codified in § 312.47(b)(1). This includes provision for documenting the agreements reached at the meeting. In order to provide the broadest possible expertise available, FDA may invite to the meeting one or more of its advisory committee members or other scientific consultants. The sponsor may, of course, also bring scientific consultants to the meeting.

With respect to study design, the agency recognizes that there has been some confusion about the role of placebo-controlled studies in patients with a life-threatening disease. FDA believes that a requirement for placebo-controlled studies is *not* appropriate in those situations where there is known to be an effective therapy, for the stage of disease or condition under investigation, that can improve survival or prevent irreversible morbidity. For example, in the case of symptomatic AIDS or advanced AIDS-related complex (ARC), where zidovudine is known to improve survival, it would not be appropriate to compare a new drug with placebo. Rather, the new drug should be compared with zidovudine. It would also be possible to compare the new drug plus zidovudine with zidovudine alone, but in neither case would it be necessary to deny patients therapy with zidovudine which is known to improve survival. In contrast, where no therapy has been shown to be effective, it is scientifically and ethically appropriate

to randomize patients to test drug and placebo. This was done with zidovudine and, by providing early and clear evidence of benefit in terms of improved survival, enabled FDA to confer the rapid approval that made the drug widely available to AIDS patients.

The Institute of Medicine, in its recent report entitled, "Confronting AIDS: Update 1988," emphasized the importance of controlled clinical trials as the "fastest, most efficient way to determine what treatments work" (Executive Summary at page 19; Report at page 139) (Ref. 10). As the report continues, "Conducting well-designed trials from the beginning will benefit more patients, sooner, than any other approach. Poorly designed trials, or administering drugs without controls and 'observing' the course of the disease, risk being inconclusive or drawing incorrect conclusions." (Report at page 139) (Ref. 10). FDA fully supports the early initiation of well-designed phase 2 controlled clinical trials as the most efficient mechanism of evaluating treatments for the desperately ill.

When planning phase 2 studies, it will be particularly important to make optimal use of pharmacokinetic/pharmacodynamic studies carried out in phase 1. Such phase 1 data are particularly useful in selecting the best dose(s) and dosing intervals for phase 2 testing. Therefore, FDA input should be helpful in the design of phase 1 studies also.

FDA can also make the drug development process more efficient by interacting with the drug sponsor, even before phase 1 testing begins, to help identify the animal studies necessary to assess the toxicity of the new drug and assure that clinical studies can be initiated with reasonable assurance of safety. In consulting with sponsors on animal studies, FDA takes into account the seriousness of the disease to be treated and the nature of the clinical studies planned. In this way, FDA involvement can facilitate the initiation of trials in human patients as early as the safety studies in animals permit, thereby reducing potential barriers to innovation at this early but important stage of new pharmaceutical development.

For example, using this process, some new AIDS drugs have been able to enter clinical testing after animal studies that were 4 weeks long or less in duration, and the preclinical animal studies completed before initial human use of zidovudine were 2 to 4 weeks long. By working closely with the sponsor, FDA can suggest the minimum amount of preclinical testing needed to go forward without compromising the safety of

clinical study participants. Unnecessary animal studies can be avoided, animal lives can be spared, and the sponsor can move the drug into clinical testing in the shortest possible time. Moreover, early FDA involvement can also shorten the time it takes the agency to review and IND submission and lessen the likelihood of FDA placing the application on clinical hold.

2. *Treatment IND's.* Section 312.83 of the rule outlines the role of the treatment IND in the context of this overall program. As codified in §§ 312.34 and 312.35, treatment IND's are intended to permit the wider use of promising experimental drugs for serious and immediately life-threatening illnesses in patients who lack satisfactory alternative therapy. Within the drug development process, treatment IND's can provide a bridge between the completion and initial analysis of promising phase 2 studies and the point of marketing approval. Thus, when early evidence from phase 2 indicates that a drug for a life-threatening or severely-debilitating illness is promising, FDA will actively work with the sponsor to evaluate the appropriateness of a treatment protocol. This approach was used during the development of zidovudine, and allowed wide availability of the drug to over 4,000 patients while the marketing application was being assembled by the sponsor and reviewed by FDA. In addition, FDA will continue to work actively to educate physicians and drug sponsors on how to utilize the treatment IND process most effectively.

3. *Risk-benefit analysis.* Section 312.84(a) of the rule provides that FDA's application of the statutory standards for marketing approval shall recognize the need for a medical risk-benefit judgment in making the final decision on approvability. As part of this evaluation, consistent with the statement of purpose in § 312.80, FDA will consider whether the benefits of the drug outweigh the known and potential risks of the drug and the need to answer remaining questions about risks and benefits of the drug, taking into consideration the severity of the disease and the absence of satisfactory alternative therapy.

While the statute uses the terms safety and effectiveness, rather than risks and benefits, the decision on whether to approve a drug inherently represents a medical risk-benefit judgment. The agency recognizes that safety and effectiveness are not absolute (i.e., not all drugs are free of risk or have unequivocal benefits), but must be assessed in light of what condition the drug treats. This is particularly true in the case of drugs to

treat life-threatening diseases, where drugs that are quite toxic may nevertheless be considered safe under the circumstances.

In carrying out the statutory mandate, FDA will consider the seriousness of the disease being treated in balancing risks and benefits. For example, as a class, oncologic drugs are highly toxic, but this is acceptable when they are used to treat illnesses for which they represent the only available method of treatment and when they can have a favorable influence on survival or on intractable symptoms. Moreover, dramatic responses (i.e., great benefit), especially on significant end points like survival or progression to an inevitably fatal stage of illness, make it easier to conclude that the benefits of treatment outweigh its risks, even if not all important questions about the drug are answered. Clearly, for a life-threatening illness, a relatively high level of known risk and some uncertainty about potential risk from the drug can be acceptable in exchange for the improved survival provided by effective drug treatment for a condition that, left untreated, would result in death. Similarly, for the same life-threatening illnesses, evidence of effectiveness must be weighed against risks of the drug and the knowledge that death would result in the absence of treatment.

Section 312.84(b) of the rule provides that the agency will usually seek the advice of outside expert consultants or advisory committees in reaching its conclusions. That section also provides that FDA will notify the members of the relevant standing advisory committee of the filing of a marketing application covered by this rule, and its availability for review.

In seeking to utilize phase 2 data for final decisionmaking, FDA would be trying to increase the likelihood that a safe and effective drug, especially one that affects mortality or major irreversible morbidity, would be shown safe and effective in the shortest possible time by assuring that the initial studies are adequate to do this—i.e., to provide evidence, even though derived from a limited data base, that would be sufficient to reach a benefit-risk judgment. FDA's goal is to be able to reach a scientifically defensible decision based on the results of well-designed phase 2 controlled clinical trials. If, on the basis of phase 2 testing, a therapy is found to effectively treat a life-threatening disease for which no other therapy exists, it would not be appropriate to continue premarketing research into phase 3. However, poorly

designed phase 2 studies serve to retard the drug development process.

If FDA concludes that the data presented are not sufficient for marketing approval, § 312.84(b) of the rule provides that FDA will issue a letter to the sponsor describing the deficiencies in that application, including why the results of the research design agreed to under § 312.82 of this rule, or in subsequent meetings, did not provide sufficient evidence for marketing approval. Such letter will also describe any recommendations made by the advisory committee regarding the application.

To increase the likelihood that phase 2 testing can provide sufficient results, sponsors could need to plan phase 2 studies that are somewhat larger and more extensive than is currently the norm, including a mode for replication of key findings. Moreover, to avoid missing an effect by using too little drug, or to avoid studying a dose that proves toxic, it may be necessary to study several doses in the first formal trials, an approach that may require a larger study but can plainly save time, thereby enabling physicians to treat patients with life-threatening illnesses more rapidly. However, it should be appreciated that is a drug has only minor or inconsistent therapeutic benefits, its positive effects may be missed in this stage of clinical testing, even if the drug ultimately proves to be beneficial following more extensive phase 3 trials.

The issue of replication requires careful consideration. The requirement in the statute for adequate and well-controlled "clinical investigations" (21 U.S.C. 355(d) (emphasis added)) has long been interpreted to mean that the effectiveness of a drug should be supported by more than one well-controlled clinical trial and carried out by independent investigators. This interpretation is also consistent with the general scientific demand for replicability to ensure reliability of study results. Therefore, as a general requirement, the clinical trials submitted in a marketing application—including trials on products covered by this rule—must include studies by more than one independent investigator, each of whom has studied a number of patients adequate to generate statistically reliable results.

When applying the statutory requirement of "adequate and well-controlled investigations" to a drug for a life-threatening or severely-debilitating disease, FDA will consider the quality of the data submitted, including the assurance of the data's consistency, reliability, and reproducibility. There

have been a few unusual instances in which a particularly persuasive multi-center study has been accepted in support of a claim of increased survival because the study was, due to its design and dramatic and reliable results, considered highly persuasive; therefore, replication was not required for ethical reasons. One such example was the approval of zidovudine to treat AIDS patients (discussed earlier in this preamble). A second example involved the approval of timolol for reduction of post-infarction mortality, where a major effect on mortality was demonstrated in a large multi-center study. The timolol study was very persuasive because of excellent design, minimal or no problems during execution of the study, and a high degree of statistical significance associated with the critical finding.

In both these instances, the sufficiency of a multi-center study for marketing approval was based on the research being well-designed and well-conducted, and a dramatic increase in survival of the patients using the drug. Under these circumstances, FDA believed it would be unethical to repeat the trial. FDA would consider applying the same principle to other such cases in which the outcome of a multi-center study demonstrated a consistently dramatic increase in survival among independently evaluable study sites and where repetition of the study would be unethical. However, the agency cautions that persuasively dramatic results are rare and that two entirely independent studies will generally be required. Sponsors should therefore plan in advance a strategy for replication of key findings through a second well-controlled study. Such replication need not delay approval where a sponsor carries out all necessary clinical studies concurrently.

Finally, § 312.84(d) of the rule provides that marketing applications submitted under the procedures contained in this section will be subject to the requirements and procedures contained in 21 CFR Part 314 or Part 600, as well as those in this interim rule. FDA has also added a conforming amendment to § 314.125 of the new drug application regulations, noting that for drugs intended to treat life-threatening or severely-debilitating illnesses that are developed in accordance with §§ 312.80 through 312.88, the criteria contained in paragraphs (b)(3), (4), and (5) of § 314.125 shall be applied according to the considerations contained in § 312.84.

While FDA can contribute to the design of the controlled clinical trials, and actively urge that such trials be pursued, the agency has no direct

control over the pace at which trials are initiated and completed. Success of drug development depends on the willingness of the sponsor and clinical investigators to devote the necessary time and resources to complete the studies expeditiously.

4. Phase 4 studies. Section 312.85 of the rule describes the role of phase 4 studies in this program. If FDA approval is gained on the basis of limited, but sufficient, clinical trials, it will usually be important to conduct postmarketing (phase 4) clinical studies that will extend the knowledge about the drug's safety and efficacy and allow physicians to optimize its use. For example, in the case of zidovudine, early appearance of a dramatic improvement in survival of the treated patients was taken as clear evidence that, for the relatively advanced HIV-infected patients treated, the benefits clearly outweighed the risks. Although significant side effects of zidovudine were found, the clinically demonstrated benefit of prolonged survival clearly outweighed those risks.

This does not mean that all important questions were answered at the time of approval of zidovudine and that research into its use could end. It was critical to examine—after marketing—its use in earlier stages of the disease, where its toxicity might outweigh its benefit (i.e., in earlier stages of the disease, survival is much greater without treatment so that there is less improvement possible, but toxicity might be just as severe). It was also important to explore dosing regimens that might be less toxic and equally effective. In addition, as with any drug, it is important to consider whether there are long-term adverse effects that might "take away" the early gain. As with zidovudine, FDA has generally been able to obtain a voluntary agreement with drug sponsors about the need to do such followup studies and the nature of their design, because sponsors also recognize important gaps in the data base and believe they need to be filled. Section 312.85 of the rule codifies this practice.

5. Focused FDA regulatory research. The responsibility for conducting the preclinical and clinical testing needed to gain marketing approval clearly rests with the drug's sponsor. This rule does not alter that responsibility. Recognizing the lack of available therapy for certain life-threatening and severely-debilitating illnesses, § 312.86 of the rule provides that in certain circumstances FDA may, in its discretion, undertake research on critical rate-limiting aspects of the preclinical, chemical/manufacturing,

and clinical phases of drug development and evaluation. For example, FDA often needs specific information upon which critical regulatory decisions are made—e.g., manufacturing standards and assays for vaccine or biotechnology products. Recent examples include FDA potency testing of vaccines and development of assay methods for drug bioavailability. FDA is prepared to intensify this practice on a limited basis as a means of meeting a public health need in facilitating the development of therapies to treat life-threatening illnesses, rather than merely waiting passively.

6. *Active monitoring of conduct and evaluation of clinical trials.* Section 312.87 of the rule provides that the Commissioner and other agency officials will actively monitor the progress of the conduct and evaluation of clinical trials and be involved in stimulating their appropriate progress. Recognizing that people with life-threatening diseases face a catastrophic condition that requires special attention, it is imperative that the conduct of clinical trials and FDA's evaluation of them proceed as expeditiously as possible. FDA actions would include, for example, contacting the sponsor directly when clinical trials are not proceeding on schedule. FDA may also convene special meetings of its advisory committees, as necessary, rather than waiting for the next scheduled periodic meeting.

Finally, FDA, in conjunction with other Public Health Service agencies, will utilize, to the extent possible, clearinghouse mechanisms for informing physicians and patients of investigational therapies for life-threatening illnesses. Existing mechanisms of this type will be augmented, as appropriate.

7. *Safeguards for patient safety.* If successfully implemented, this program will expedite the availability and approval of new therapies for life-threatening and severely-debilitating illnesses while assuring that the products are shown safe and effective under the law. Section 312.88 of the rule references safeguards inherent in FDA regulations that ensure the safety of clinical testing and the safety of products following marketing approval. These include the requirements for informed consent (21 CFR Part 50) and institutional review boards (21 CFR Part 56). These safeguards further include the review of animal studies prior to initial human testing (§ 312.23); IND safety reports during the conduct of clinical trials and treatment IND protocols (§ 312.32); safety update reports during

the review of marketing applications (§ 314.50); and adverse drug reaction reports after products are approved for marketing (§ 314.80).

In addition to these regulatory safeguards designed to assure patient safety, FDA's practices and procedures provide additional safeguards to assure the quality and integrity of the drug development and review process. These include conducting on-site audits of key studies and/or clinical investigators to assure authenticity of the data submitted to FDA, and inspections of manufacturing facilities before marketing approval is granted to assure that manufacturers are able to produce properly formulated compounds.

D. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

E. Economic Impact

FDA has considered the economic impacts of this interim rule and concludes that additional costs resulting from this rule will be negligible, and to the limited extent that they may occur, they will likely be more than off-set by the societal benefits of this rule.

The compression of the drug development process set forth in this rule for life-threatening and severely-debilitating illnesses presents a trade-off for affected sponsors. They would be relieved of conducting the customary phase 2/phase 3 clinical studies if they participate in early study design consultation with FDA, conduct a sufficiently comprehensive phase 2 study, and stand ready to conduct any necessary phase 4 studies. Considering the probable time savings of this process, it is expected that the net cost of clinical development and regulatory review for a sponsor will remain constant or possibly decrease. Even if costs were to increase slightly, the societal benefits would more than likely compensate for any added costs since a considerable patient population would be receiving the life-saving benefits of the expedited therapy over an extended period of time that would not otherwise be realized.

Accordingly, FDA concludes that this interim rule is not a major rule as defined by Executive Order 12291, which would require a regulatory flexibility analysis. Furthermore, this rule is not expected to impose substantial impacts on a significant

number of small entities which would require a regulatory flexibility analysis under the requirements of the Regulatory Flexibility Act of 1980.

F. Paperwork Reduction Act of 1980

This interim rule does not contain new collection of information requirements. Section 312.88 does refer to regulations that contain collection of information requirements that were previously submitted for review to the Director of the Office of Management and Budget (OMB) under section 3504 of the Paperwork Reduction Act of 1980. Sections 312.23 and 312.32 were approved under OMB control number 0910-0014. Section 314.50 was approved under OMB control number 0910-0001. Section 314.80 was approved under OMB control number 0910-0230.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Young, Frank E., and Stuart L. Nightingale, "FDA's Newly Designated Treatment IND's," "Information on Treatment IND's as They Become Available to the Practitioner," *Journal of the American Medical Association*, 260:224-225, 247, 1988.
2. Young, Frank E., John A. Norris, Joseph A. Levitt, and Stuart L. Nightingale, "The FDA's New Procedures for the Use of Investigational Drugs in Treatment," *Journal of the American Medical Association*, 259:2267-2270, 1988.
3. "Drugs Hold Hope for Parkinson's Obsessive-Compulsive Patients," *FDA Consumer*, September 1988:31.
4. Young, Frank E., "Experimental Drugs for the Desperately Ill: A Progress Report," *FDA Consumer*, May 1988:2-3.
5. "Updates," *FDA Consumer*, February 1988:2-3.
6. Young, Frank E., "New Drug Development in the United States," *FDA Consumer*, November 1987:4-5.
7. "Updates," *FDA Consumer*, September 1987:5-6.
8. Young, Frank E., "Experimental Drugs for the Desperately Ill," *FDA Consumer*, June 1987:2-3.
9. Office of Planning and Evaluation Study 77, "The Outcome of Research on New Molecular Entities Commencing Clinical Research in the Years 1976-78," FDA, May 1988.
10. "Confronting AIDS: Update 1988," Institute of Medicine, 1988.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, Parts 312 and 314 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. Subparts E and F are redesignated as Subparts F and G, respectively, and new Subpart E is added consisting of §§ 312.80 through 312.88 to read as follows:

Subpart E—Drugs Intended To Treat Life-Threatening and Severely-debilitating Illnesses

- Sec.
 312.80 Purpose.
 312.81 Scope.
 312.82 Early consultation.
 312.83 Treatment protocols.
 312.84 Risk-benefit analysis in review of marketing applications for drugs to treat life-threatening and severely-debilitating illnesses.
 312.85 Phase 4 studies.
 312.86 Focused FDA regulatory research.
 312.87 Active monitoring of conduct and evaluation of clinical trials.
 312.88 Safeguards for patient safety.
 Authority: Secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049-1053 as amended, 1055-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262); 21 CFR 5.10, 5.11.

Subpart E—Drugs Intended To Treat Life-Threatening and Severely-debilitating Illnesses**§ 312.80 Purpose.**

The purpose of this section is to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists. As stated § 314.105(c) of this chapter, while the statutory standards of safety and effectiveness apply to all drugs, the many kinds of drugs that are subject to them, and the wide range of uses for those drugs, demand flexibility in applying the standards. The Food and Drug Administration (FDA) has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness. These procedures reflect the recognition that physicians and patients are generally willing to accept greater risks or side

effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious illnesses. These procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated. The procedure outlined in this section should be interpreted consistent with that purpose.

§ 312.81 Scope.

This section applies to new drug, antibiotic, and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely-debilitating diseases.

(a) For purposes of this section, the term "life-threatening" means:

- (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and
- (2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

(b) For purposes of this section, the term "severely debilitating" means diseases or conditions that cause major irreversible morbidity.

(c) Sponsors are encouraged to consult with FDA on the applicability of these procedures to specific products.

§ 312.82 Early consultation.

For products intended to treat life-threatening or severely-debilitating illnesses, sponsors may request to meet with FDA-reviewing officials early in the drug development process to review and reach agreement on the design of necessary preclinical and clinical studies. Where appropriate, FDA will invite to such meetings one or more outside expert scientific consultants or advisory committee members. To the extent FDA resources permit, agency reviewing officials will honor requests for such meetings.

(a) *Pre-investigational new drug (IND) meetings.* Prior to the submission of the initial IND, the sponsor may request a meeting with FDA-reviewing officials. The primary purpose of this meeting is to review and reach agreement on the design of animal studies needed to initiate human testing. The meeting may also provide an opportunity for discussing the scope and design of phase 1 testing, and the best approach for presentation and formatting of data in the IND.

(b) *End-of-phase 1 meetings.* When data from phase 1 clinical testing are available, the sponsor may again request a meeting with FDA-reviewing officials. The primary purpose of this meeting is to review and reach

agreement on the design of phase 2 controlled clinical trials, with the goal that such testing will be adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing. The procedures outlined in § 312.47(b)(1) with respect to end-of-phase 2 conferences, including documentation of agreements reached, would also be used for end-of-phase 1 meetings.

§ 312.83 Treatment protocols.

If the preliminary analysis of phase 2 test results appears promising, FDA may ask the sponsor to submit a treatment protocol to be reviewed under the procedures and criteria listed in §§ 312.34 and 312.35. Such a treatment protocol, if requested and granted, would normally remain in effect while the complete data necessary for a marketing application are being assembled by the sponsor and reviewed by FDA (unless grounds exist for clinical hold of ongoing protocols, as provided in § 312.42(b)(3)(ii)).

§ 312.84 Risk-benefit analysis in review of marketing applications for drugs to treat life-threatening and severely-debilitating illnesses.

(a) FDA's application of the statutory standards for marketing approval shall recognize the need for a medical risk-benefit judgment in making the final decision on approvability. As part of this evaluation, consistent with the statement of purpose in § 312.80, FDA will consider whether the benefits of the drug outweigh the known and potential risks of the drug and the need to answer remaining questions about risks and benefits of the drug, taking into consideration the severity of the disease and the absence of satisfactory alternative therapy.

(b) In making decisions on whether to grant marketing approval for products that have been the subject of an end-of-phase 1 meeting under § 312.82, FDA will usually seek the advice of outside expert scientific consultants or advisory committees. Upon the filing of such a marketing application under § 314.101 or Part 601 of this chapter, FDA will notify the members of the relevant standing advisory committee of the application's filing and its availability for review.

(c) If FDA concludes that the data presented are not sufficient for marketing approval, FDA will issue (for a drug) a not approvable letter pursuant to § 314.120 of this chapter, or (for a biologic) a deficiencies letter consistent with the biological product licensing procedures. Such letter, in describing the

deficiencies in the application, will address why the results of the research design agreed to under § 312.82, or in subsequent meetings, have not provided sufficient evidence for marketing approval. Such letter will also describe any recommendations made by the advisory committee regarding the application.

(d) Marketing applications submitted under the procedures contained in this section will be subject to the requirements and procedures contained in Part 314 or Part 600 of this chapter, as well as those in this subpart.

§ 312.85 Phase 4 studies.

Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.

§ 312.86 Focused FDA regulatory research.

At the discretion of the agency, FDA may undertake focused regulatory research on critical rate-limiting aspects

of the preclinical, chemical/manufacturing, and clinical phases of drug development and evaluation. When initiated, FDA will undertake such research efforts as a means for meeting a public health need in facilitating the development of therapies to treat life-threatening or severely debilitating illnesses.

§ 312.87 Active monitoring of conduct and evaluation of clinical trials.

For drugs covered under this section, the Commissioner and other agency officials will monitor the progress of the conduct and evaluation of clinical trials and be involved in facilitating their appropriate progress.

§ 312.88 Safeguards for patient safety.

All of the safeguards incorporated within Parts 50, 56, 312, 314, and 600 of this chapter designed to ensure the safety of clinical testing and the safety of products following marketing approval apply to drugs covered by this section. This includes the requirements for informed consent (Part 50 of this chapter) and institutional review boards (Part 56 of this chapter). These safeguards further include the review of animal studies prior to initial human testing (§ 312.23), and the monitoring of adverse drug experiences through the requirements of IND safety reports (§ 312.32), safety update reports during agency review of a marketing

application (§ 314.50 of this chapter), and postmarketing adverse reaction reporting (§ 314.80 of this chapter).

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

2. The authority citation for 21 CFR Part 314 continues to read as follows:

Authority: Secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049-1053 as amended, 1055-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371); 21 CFR 5.10, 5.11.

3. Section 314.125 is amended by adding paragraph (c) to read as follows:

§ 314.125 Refusal to approve an application.

* * * * *

(c) For drugs intended to treat life-threatening or severely-debilitating illnesses that are developed in accordance with §§ 312.80 through 312.88 of this chapter, the criteria contained in paragraphs (b) (3), (4), and (5) of this section shall be applied according to the considerations contained in § 312.84 of this chapter.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: October 18, 1988.

[FR Doc. 88-24457 Filed 10-19-88; 10:18 am]

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Registered Federal Reporter

**Friday
October 21, 1988**

Part VII

**Department of Defense
General Services
Administration**

**National Aeronautics and
Space Administration**

48 CFR Part 31

**Federal Acquisition Regulation (FAR);
Public Relations Costs; Proposed Rule**

October 21, 1966

Dear Sir:

I am pleased to inform you that the Department of Defense has received your letter of October 10, 1966, regarding the proposed rulemaking for the Federal Acquisition Regulation (FAR).

The Department is currently reviewing the proposed rulemaking and will be in a position to provide a response to you by the end of the month.

I am sure that you will understand the need for a thorough review of the proposed rulemaking and the importance of providing a complete and accurate response.

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DEPARTMENT OF DEFENSE**GENERAL SERVICES
ADMINISTRATION****NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION****48 CFR Part 31****Federal Acquisition Regulation (FAR);
Public Relations Costs**

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to FAR 31.205-1 to delete paragraph (h) which deals with the relationship between the cost principle entitled "Public Relations and Advertising Costs" and the other cost principles.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before December 20, 1988 to be considered in the formulation of a final rule.

ADDRESS: Interest parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Street NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 88-33 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Margaret A. Willis, FAR Secretariat, Room 4041, GS Building, Washington, DC 20405, (202) 523-4755.

SUPPLEMENTARY INFORMATION:**A. Background**

Federal Acquisition Circular (FAC) 84-37 revised FAR 31.204 to provide guidelines on determining the allowability of costs to which more than one cost principle is relevant. The Councils are now proposing to delete the current coverage at FAR 31.205-1(h) as inconsistent with the new coverage at FAR 31.204.

B. Regulatory Flexibility Act

The proposed change to FAR 31.205-1 is not expected to have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C., 601, et seq.) because most contract awarded to small entities are awarded on a competitive fixed-price basis and the cost principles do not apply.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed change does not impose recordkeeping information collection requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, et seq.

List of Subjects in 48 CFR Part 31

Government procurement.

Dated: October 13, 1988.

Harry S. Rosinski,

Acting Director, Office of Federal Acquisition and Regulatory Policy.

Therefore, it is proposed that 48 CFR Part 31 be amended as set forth below:

**PART 31—CONTRACT COST
PRINCIPLES AND PROCEDURES**

1. The authority citation for 48 CFR Part 31 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c)

31.205-1 [Amended]

2. Section 31.205-1 is amended by removing paragraph (h).

[FR Doc. 88-24413 Filed 10-20-88; 8:45 am]

BILLING CODE 6820-61-M