

(c) An investigational drug for use in a phase 1 study, as described in § 312.21(a) of this chapter, is subject to the statutory requirements set forth in 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in part 211 of this chapter. However, this exemption does not apply to an investigational drug for use in a phase 1 study once the investigational drug has been made available for use by or for the sponsor in a phase 2 or phase 3 study, as described in § 312.21(b) and (c) of this chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a phase 2 or phase 3 study or the drug has been lawfully marketed, the drug for use in the phase 1 study must comply with part 211.

Dated: July 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

28 CFR Part 0

[Docket No. DEA-310F]

Redelegation of Functions

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This rule makes one revision to the Drug Enforcement Administration's (DEA) regulations concerning agency management. Additional personnel are authorized to sign and issue administrative subpoenas.

DATES: *Effective Date:* July 15, 2008.

FOR FURTHER INFORMATION CONTACT: Wendy H. Goggin, Chief Counsel, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-1000.

SUPPLEMENTARY INFORMATION: This Final Rule implements one change to Title 28, Code of Federal Regulations (CFR), Part 0 by adding three officials to the list of officials who may sign and issue administrative subpoenas pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513, 84 Stat. 1236 (1970), as amended (the Act), codified at 21 U.S.C. 801-971. In addition to the Attorney General and the DEA

Administrator, the current list of such officials is set forth at 28 CFR, Chapter I, part 0, Appendix to Subpart R, Section 4. Title 21, U.S.C. 875 and 876, provide the authority to issue such subpoenas. By 28 CFR 0.100, the Attorney General has delegated this authority to issue administrative subpoenas in support of his functions and duties under the Act to the DEA Administrator. The DEA Administrator is permitted by 28 CFR 0.104 to redelegate this authority "to any of [her] subordinates[.]"

By this Final Rule, DEA now extends this administrative subpoena authority to its senior officials overseas who often supervise investigations with leads back in the United States, *i.e.*, DEA's Regional Directors, Assistant Regional Directors, and Country Attachés. As Title 28 CFR, Chapter I, Part 0, Appendix to Subpart R, Section 4 is presently written, DEA Resident Agents in Charge and Special Agent Group Supervisors posted outside the United States have such authority while their superiors, *i.e.*, Regional Directors, Assistant Regional Directors, and Country Attachés, do not. The amendment to section 4 is designed, in part, to rectify this anomaly.

Title 28 CFR, Chapter I, Part 0, Appendix to Subpart R, Section 4 currently lists twelve categories of DEA and FBI officials who are empowered to sign and issue administrative subpoenas under 21 U.S.C. 875 and 876. To this list of senior officials DEA now adds its Regional Directors, Assistant Regional Directors, and Country Attachés. This is being done to rectify an oversight. While both DEA Resident Agents in Charge and Special Agent Group Supervisors posted outside the U.S. have authority to sign and issue administrative subpoenas, unlike the case of Resident Agents in Charge and Special Agent Group Supervisors within the U.S., the superior officials (Regional Directors, Assistant Regional Directors, and Country Attachés) of such Resident Agents in Charge and Group Supervisors serving overseas have not heretofore been listed at Title 28 CFR, Chapter I, Part 0, Appendix to Subpart R, Section 4, as officials to whom the Administrator has redelegated her authority to sign and issue administrative subpoenas.

Regulatory Certifications

Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, and practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay

in effective date. See 5 U.S.C. 553(a)(2), (b)(3)(A), (d)(3).

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612, has reviewed this rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Drug Enforcement Administration. Further, a Regulatory Flexibility Analysis was not required to be prepared for this final rule because the Drug Enforcement Administration was not required to publish a general notice of proposed rulemaking for this matter.

Executive Order 12866

This rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation. This rule is limited to agency organization, management and personnel as described by Executive Order 12866 section (3)(d)(3) and, therefore, is not a "regulation" or "rule" as defined by that Executive Order. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rule will 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 13132, Federalism, the Drug Enforcement Administration has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$120 million or more (adjusted for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates

Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

Congressional Review Act

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

The Drug Enforcement Administration has determined that this action is a rule relating to agency organization, procedure or practice that does not substantially affect the rights or obligation of non-agency parties and, accordingly, is not a "rule" as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

■ Accordingly, and for the reasons set forth above, 28 CFR Part 0 is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE [AMENDED]

■ 1. The authority citation for Part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

■ 2. In section 4 of the Appendix to Subpart R, paragraph (a) is revised to read as follows:

Appendix to Subpart R of Part 0—Redelegation of Functions

Sec. 4. Issuance of subpoenas. (a) The Chief Inspector of the DEA; the Deputy Chief Inspectors and Associate Deputy Chief Inspectors of the Office of Inspections and the Office of Professional Responsibility of the DEA; all Special Agents-in-Charge of the DEA and the FBI; DEA Inspectors assigned to the Inspection Division; DEA Associate Special Agents-in-Charge; DEA and FBI Assistant Special Agents-in-Charge; DEA Resident Agents-in-Charge; DEA Diversion Program Managers; FBI Supervisory Senior Resident Agents; DEA Special Agent Group

Supervisors; those FBI Special Agent Squad Supervisors who have management responsibility over Organized Crime/Drug Program Investigations; and DEA Regional Directors, Assistant Regional Directors, and Country Attachés, are authorized to sign and issue subpoenas with respect to controlled substances, listed chemicals, tableting machines or encapsulating machines under 21 U.S.C. 875 and 876 in regard to matters within their respective jurisdictions.

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Dated: July 1, 2008.

Michele M. Leonhart,

Acting Administrator.

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in August 2008. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

DATES: Effective August 1, 2008.

FOR FURTHER INFORMATION CONTACT:

Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to part 4022).

This amendment (1) adds to Appendix B to part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during August 2008, (2) adds to Appendix B to part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during August 2008, and (3) adds to Appendix C to part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during August 2008.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 6.05 percent for the first 20 years following the valuation date and 5.12 percent thereafter. These interest assumptions represent an increase (from those in effect for July 2008) of 0.10 percent for the first 20 years following the valuation date and 0.10 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent a decrease (from those in effect for July 2008) of 0.25 percent in the immediate annuity rate and are otherwise unchanged. For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.