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FEDERAL REGISTER

Proposed Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

45 CFR Part 5b

PRIVACY ACT

Notice of Proposed Exemptions

DATE: September 5, 1975

SUMMARY: Notice is hereby given that the Secretary proposes exemptions as provided under subsections (j) and (k) of the Privacy Act, Public Law 93-579, 5 U.S.C. 552a. These exemptions are proposed in addition to those exemptions proposed in § 5b.9(b) of the Secretary's proposed regulations, implementing the Privacy Act, published in the FEDERAL REGISTER on August 14, 1975 (40 FR 34129).

The “Maryland Psychiatric…[text omitted]

The “Investigatory Material…[text omitted]

The “General Criminal…[text omitted]

Also proposed to be exempted from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f) of the Act are the “Investigatory Material…[text omitted]

As provided in subsections (j)(2), (k)(2) and (5) of the Act, the “Clinical Investigator Records, HEW/FDA,” the “Regulated Industry Employee Enforcement Records, HEW/FDA,” and the “employee, consultant, contractor security and investigative records,” systems of records maintained by the Food and Drug Administration, are proposed to be exempted from subsections (c)(3), (d)(1) through (4) and (f), (e)(4)(G) and (H), and (e)(3) of the Act. The Commissioner of Food and Drugs is proposing regulations to implement the Privacy Act as it will affect systems of records maintained by the Food and Drug Administration. Also included in these proposed regulations are those systems of records maintained by the Food and Drug Administration proposed to be exempted in this notice. The proposed Food and Drug Administration regulations should be consulted for a full statement of the rationale and justification for the exemptions.

Interested persons and organizations are invited to submit written comments on these proposed exemptions to the Director, Fair Information Practices Staff, Department of Health, Education, and Welfare, 330 Independence Avenue, S.W., Washington, D.C. 20201.

All comments received on or before September 17, 1975 will be considered by the Secretary before taking action on the proposed exemptions, and will be available for public inspection in Room 4513, at the above address.

These exemptions are proposed under the authority of subsections (j) and (k) of 5 U.S.C. § 552a and 5 U.S.C. § 301.

In consideration of the foregoing, it is proposed to amend part 5b of 45 CFR Subtitle A (40 FR 34129) as follows:

PART 5b—PRIVACY ACT REGULATION

1. By adding paragraphs (b)(2)(iv), (3), (4), (5), (6) and (c) as follows:

§ 5b.9 Exemptions.
(b) * * *
(2) * * *
[text omitted]
(3) As provided in subsection (j)(2) of the Act…[text omitted]
(4) As provided in subsection (k)(2) of the Act…[text omitted
(5) As provided in subsection (k)(5) of the Act…[text omitted]
(6) As provided in subsections (j)(2), (k)(2), and (5) of the Act, the "Clinical Investigator Records, HEW/FDA," the "Regulated Industry Employee Enforcement Records, HEW/FDA," and the "employee, consultant, and contractor security and investigative records," systems of records maintained by the Food and Drug Administration, are exempt from the following provisions of the Act:
(i) 552a(c)(3) requiring that an individual be provided with the accounting of disclosures of records about himself; and
(ii) 552a(d)(1) through (4) and (f) requiring procedures for individuals to be given notification of and access to records about themselves, and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such records except where access is required under subsection (k)(2) of the Act and to the extent that access is required under subsection (k)(5) of the Act, and paragraph (c)(2) of this section; and,
(iii) 552a(e)(4)(G) and (H) regarding the inclusion in the notice for the system of information about agency procedures for notification, access, and contest; and,
(iv) 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice of a Food and Drug Administration record system notice, and the consequences to the individual of not providing the information, but only with respect to information compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.
(c) *Access*…[text omitted]

Dated: August 29, 1975.
DAVID MATHEWS,
Secretary

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