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justify withholding records and information only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld.

[70 FR 41958, July 21, 2005]

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be subject to the special requirements of part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in part 21, subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

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