

not permit the requester to directly pay or be directly charged for the service.

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■ 17. Newly redesignated § 20.46 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 20.46 Waiver or reduction of fees.

(a) *Standard.* The Assistant Commissioner for Public Affairs (or delegatee) will waive or reduce the fees that would otherwise be charged if disclosure of the information meets both of the following tests:

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§ 20.48 [Amended]

■ 18. Newly redesignated § 20.48 *Judicial review of proposed disclosure* is amended by removing “§ 20.45” and by adding in its place “§ 20.47”.

■ 19. Newly redesignated § 20.49 is amended by revising paragraphs (a) and (c) to read as follows:

§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

* * * * *

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

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§ 20.53 [Amended]

■ 20. Newly redesignated § 20.53 is amended by removing “§ 20.42” and by adding in its place “§ 20.45”.

§ 20.81 [Amended]

■ 21. Section 20.81 *Data and information previously disclosed to the public* is amended by removing paragraph (b) and by redesignating paragraph (c) as new paragraph (b).

§ 20.83 [Amended]

■ 22. Section 20.83 *Disclosure required by court order* is amended in paragraph (a) by removing “either” and by

removing the phrase “or by a written determination pursuant to the procedure established in § 20.44”.

■ 23. Section 20.107 is amended by revising paragraph (a) to read as follows:

§ 20.107 Food and Drug Administration manuals.

(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. An index of all such manuals is available by writing to the Freedom of Information Staff (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room, located in rm. 12A-30 at the same address. The index and all manuals created by the agency on or after November 1, 1996, will be made available through the Internet at <http://www.fda.gov>.

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§ 20.111 [Amended]

■ 24. Section 20.111 *Data and information submitted voluntarily to the Food and Drug Administration* is amended in paragraph (b) by removing the phrase “or by a written determination pursuant to the procedure established in § 20.44” and in paragraph (c)(4) by removing the last sentence.

■ 25. Section 20.120 is added to subpart F to read as follows:

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Food and Drug Administration operates two public reading rooms. The Freedom of Information Staff's Public Reading Room is located in rm. 12A-30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, the phone number is 301-827-6500. The Dockets Management Branch's Public Reading Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20857; the phone number is 301-827-6860. Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

(b) The following records are available at the Freedom of Information Staff's Public Reading Room:

(1) A guide for making requests for records or information from the Food and Drug Administration;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Food and Drug Administration records which have been released to any person in response to a Freedom of Information request and which the

agency has determined have become or are likely to become the subject of subsequent requests for substantially the same records;

(4) Indexes of records maintained in the Freedom of Information Staff's Public Reading Room; and

(5) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(c) The following records are available in the Dockets Management Branch's Public Reading Room:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by the agency that are still in force and not published in the **Federal Register**;

(3) Indexes of records maintained in the Dockets Management Branch's Public Reading Room; and

(4) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(d) The agency will make reading room records created by the Food and Drug Administration on or after November 1, 1996, available electronically through the Internet at the agency's World Wide Web site which can be found at <http://www.fda.gov>. At the agency's discretion, the Food and Drug Administration may also make available through the Internet such additional records and information it believes will be useful to the public.

PART 314—APPLICATION FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 26. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.65 [Amended]

■ 27. Section 314.65 *Withdrawal by the applicant of an unapproved application* is amended by removing “§ 20.42” and by adding in its place “§ 20.45”.

§ 314.72 [Amended]

■ 28. Section 314.72 *Change in ownership of an application* is amended in paragraph (a)(2)(iii) by removing “§ 20.42” and by adding in its place “§ 20.45”.

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

■ 29. The authority citation for 21 CFR part 720 continues to read as follows: