



RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

FOIA — 92-279

RESPONSE TYPE

XX FINAL

PARTIAL

DATE

JUL 21 1992

DOCKET NUMBER(S) (if applicable)

REQUESTER

Joseph M. Felton

PART I.—AGENCY RECORDS RELEASED OR NOT LOCATED (See checked boxes)

No agency records subject to the request have been located.

No additional agency records subject to the request have been located.

Requested records are available through another public distribution program. See Comments section.

Agency records subject to the request that are identified in Appendix(es) _____ are already available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.

X Agency records subject to the request that are identified in Appendix(es) A are being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.

The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.

Agency records subject to the request that are identified in Appendix(es) _____ may be inspected and copied at the NRC Local Public Document Room identified in the Comments section.

Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.

X Agency records subject to the request are enclosed. [Appendix A documents are enclosed.]

Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.

Fees

You will be billed by the NRC for fees totaling \$ _____

You will receive a refund from the NRC in the amount of \$ _____

In view of NRC's response to this request, no further action is being taken on appeal letter dated _____ No _____

PART II. A—INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

X Certain information in the requested records is being withheld from public disclosure pursuant to the exemptions described in and for the reasons stated in Part II, B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 2120 L Street, N.W., Washington, DC in a folder under this FOIA number.

COMMENTS

SIGNATURE, DIRECTOR, DIVISION OF FREEDOM OF INFORMATION AND PUBLICATIONS SERVICES

Donna H. Murphy

9301080036 920721
PDR FOIA
FELTON92-279 PDR

**RESPONSE TO FREEDOM OF
INFORMATION ACT (FOIA) REQUEST
(CONTINUATION)**

FOIA NUMBER(S)

FOIA — 92-279

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PART II B — APPLICABLE EXEMPTIONS

Records subject to the request that are described in the enclosed Appendix(es) B are being withheld in their entirety or in part under the Exemption No. (s) and for the reason(s) given below pursuant to 5 U.S.C. 552(b) and 10 CFR 9.17(a) of NRC regulations.

1 The withheld information is properly classified pursuant to Executive Order. (Exemption 1)

2 The withheld information relates solely to the internal personnel rules and procedures of NRC. (Exemption 2)

3 The withheld information is specifically exempted from public disclosure by statute indicated. (Exemption 3)

Sections 141-145 of the Atomic Energy Act, which prohibits the disclosure of Restricted Data or Formerly Restricted Data (42 U.S.C. 2161-2165)

Section 147 of the Atomic Energy Act, which prohibits the disclosure of Unclassified Safeguards Information (42 U.S.C. 2167).

4 The withheld information is a trade secret or commercial or financial information that is being withheld for the reason(s) indicated. (Exemption 4)

The information is considered to be confidential business (proprietary) information.

The information is considered to be proprietary information pursuant to 10 CFR 2.790(d)(1).

The information was submitted and received in confidence pursuant to 10 CFR 2.790(d)(2).

☒ 5 The withheld information consists of interagency or intraagency records that are not available through discovery during litigation. (Exemption 5). Applicable Privilege:

☒ Deliberative Process: Disclosure of predecisional information would tend to inhibit the open and frank exchange of ideas essential to the deliberative process. Where records are withheld in their entirety, the facts are inextricably intertwined with the predecisional information. There also are no reasonably segregable factual portions because the release of the facts would permit an indirect inquiry into the predecisional process of the agency.

☒ Attorney work product privilege. (Documents prepared by an attorney in connection with litigation.)

☒ Attorney-client privilege. (Confidential communications between an attorney and his/her client.)

6 The withheld information is exempted from public disclosure because its disclosure would result in a clearly unwarranted invasion of personal privacy. (Exemption 6)

7 The withheld information consists of records compiled for law enforcement purposes and is being withheld for the reason(s) indicated. (Exemption 7)

Disclosure could reasonably be expected to interfere with an enforcement proceeding because it could reveal the scope, direction, and focus of enforcement efforts, and thus could possibly allow recipients to take action to shield potential wrongdoing or a violation of NRC requirements from investigators. (Exemption 7 (A))

Disclosure would constitute an unwarranted invasion of personal privacy. (Exemption 7(C))

The information consists of names of individuals and other information the disclosure of which could reasonably be expected to reveal identities of confidential sources. (Exemption 7 (D))

OTHER

PART II C — DENYING OFFICIALS

Pursuant to 10 CFR 9.25(b) and/or 9.25(c) of the U.S. Nuclear Regulatory Commission regulations, it has been determined that the information withheld is exempt from production or disclosure, and that its production or disclosure is contrary to the public interest. The persons responsible for the denial are those officials identified below as denying officials and the Director, Division of Freedom of Information and Publications Services, Office of Administration, for any denials that may be appealed to the Executive Director for Operations (EDO).

DENYING OFFICIAL	TITLE/OFFICE	RECORDS DENIED	APPELLATE OFFICIAL		
			EDO	SECRETARY	IG
Robert Bernero	Director, NMSS	Appendix B	<input checked="" type="checkbox"/>		

PART II D — APPEAL RIGHTS

The denial by each denying official identified in Part II C may be appealed to the Appellate Official identified there. Any such appeal must be made in writing within 30 days of receipt of this response. Appeals must be addressed, as appropriate, to the Executive Director for Operations, to the Secretary of the Commission, or to the Inspector General, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should clearly state on the envelope and in the letter that it is an "Appeal from an Initial FOIA Decision."

Re: FOIA-92-279

APPENDIX A
DOCUMENTS BEING PLACED IN THE PDR

NUMBER	DATE	DESCRIPTION
1.	Undated	Enclosures III and IV to 5/5/92 letter from John Glenn to USFDA: Enclosure III - "Summary of the Nature of Departures from Radiopharmaceutical Package Inserts Made by Medical Licensees," and Enclosure IV - "Departure Requests." (42 pages)
2.	Various	10 CFR Parts 30, 32 & 35. (12 pages)

Re: FOIA-92-279

APPENDIX B
DOCUMENTS BEING WITHHELD IN THEIR ENTIRETY

NUMBER	DATE	DESCRIPTION
1.	4/3/92	Letter from Robert Bernero to Carl Peck, USFDA. (1 page) Exemption 5
2.	4/15/92	Preliminary Summary Departures Made Under the Interim Final Rule. (3 pages) Exemption 5
3.	Undated	Proposed Agenda - Joint NRC/FDA Meeting April 16, 1992. (1 page) Exemption 5
4.	4/16/92	Enclosures I and II to 5/5/92 letter from John Glenn, NMSS to USFDA: Enclosure I - "April 16, 1992 Preliminary Summary Departures Made Under the Interim Final Rule," and Enclosure II - "U.S. Nuclear Regulatory Commission Licensee Inspection Results for Radiopharmaceutical Package Insert Departures Under Interim Final Rule, April 29, 1992." (2 pages) Exemption 5
5.	5/5/92	Letter from John E. Glenn, NMSS, to Wiley Chambers, USFDA. (1 page) Exemption 5
6.	5/5/92	Letter from John E. Glenn, NMSS, to Wiley Chambers, USFDA. (1 page) Exemption 5
7.	Undated	Draft Proposed Rule: Elimination of Recordkeeping Requirements Associated With the Interim Final Rule. (3 pages) Exemption 5