§10.85 Advisory Opinions,

Address to Commissioner-
Petitions
Division of Dockets Management,
Food and Drug Administration Department
of Health and Human Services. 5630
Fishers lane. rm. 1061
Rockville. MD 20852

Jan 3, 2005
Date Filed.

2004P-0003
Petition.

Request For Advisory Opinion,

Commissioner-
The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drug's and Device's with respect to (Public Health service Act,) (42 U.S.C 262)(a) with respect to a biological Product (the general nature of the matter involved). A Issues involved Clearly Formulated in an expermental Protocol implanted in a incarcerated Patient. Biomedical research involving a expermental device. Found at Title 21 code of Federal Regulations 888.3300 Hip Joint metal constrained cemented or uncemented Prosthesis without bone cement §888.3027 - This device is not intended For biological Fixation. class -3 device. 52 FR 33702 Sept 4. 1987 as amended at 61 FR 50709 sept. 27. 1996 - 21 C.F.R ch. 1 4-1-04 Edition Food and Drug Administration. HHS B-statement of Facts and law. Background Page-4. Federal Food. Drug and Cosmetic Act the Act as amended by the Safe Medical Devices Act of 1990 the Medical Device Amendments of 1992 and the Food and Drug Modernization Act of 1997 the modernization Act contain Provisions related to all products under F.D.A's API Jurisdiction each device-related section set Forth Agency Policy For implementation,

2005A-0014

The requirements that apply to third Party and Hospital reprocessors are:

1 Medical Device Reporting section 510 of the Act: 21 C.F.R (Part 803)

2. Medical Device Tracking section 519e of the Act: 21 C.F.R (Part 821) (subPart-B (821.20) (821.25)

3. Medical Device Corrections and Removels section (519F) of the Act: 21 C.F.R (Part 806)

4. Registration and listing section 510 of the Act: 21 C.F.R (Part 807)

5. Premarket Reauirements section 513 and 515 of the Act: 21 C.F.R (807) and 2(814)

6. labeling (section 502) of the Act: 21 C.F.R (801)

7. Quality System Regulation section 520F of the Act: (21 C.F.R Part 820)

8. Purpose of issuance sec. 369.1 sub A of 21 CFR Part 369 Each of these regulatory requirements is described and corresponding of the Acts setFourth F.D.A regulation in 21 C.F.R, and other F.D.A guidances. From the united states code annotated title 21 Food and Drugs note 50w. - 21 § 841 Circumstantial evidence support conclusion.

1 Health Professional Failure to release medical records to Patient. Failure to warn with intent to defraud and mislead user Patient. and wont respont to Patient or Patients Friend and Paralegal service with use of own Hospital records release AFTid

10.85 Advisory Opinion

View Page 4. Background,
The undersigned certifies that a decision involved in assigned docket numbers 2004P-0003/PRL-1 and 2004P-0003/PSA-1 and assigned docket number 2004P/0003/PSA 2 last Filed 5.14.2004

Petition requests that a subpoena beFiled on bohalf of Petitioner to obtain medical records about device with undersigned Consent, this request is in referenced with medwatch complaint 4003197 and Device Petitions that relate a life-threatening Device thats incomplete on assembly in human subject.

Documents to be Filed under 10.65h at Dockets management Branch of title 21 C.F.R 10.30 .10.33 10.35 and enforced by 10.40

signed Bill Pierson

Petitioner _ Billy G. Pierson 907177

Monitored by Federal Judge____respond.

- (Federal Food, Drug and Cosmetic Act). The Act as amended by the (Safe Medical Devices Act of 1990) and the (Medical Device Admendments of 1992) and the (Food and Drug Administration Modernization Act of 1997). The Modernization Act signed into law on Nov. 21. 1997. The Modernization Act. contains Provisions related to all Products under the F.D.A's Jurisdiction.

▷Cross References

▷Title 21 C F R 800-1299 (F.D.A Medical devices—ch. 1—4.1.04 ED)

(Part 369) (subparts A. and B) of 21 C F R 369.1 _sections 02 d Purpose of issuance. § 369.20 Warning and caution statements.

(Part 801) (subparts A-B-C-D) of 21 C F R 801.109 Prescription devices

(Part 803) of 21 C F R 803.1 _ 803.3_9_10_ Medical device reporting.

(Part 806) (subparts A, and B,) of 21 C F R 806.1 _ 806.2 and 806.10 §§ 20. .30 .40 Medical device corrections, and removals.

(Part 812) (subpart-B) of 21 C F R 81236 Treatment use of an investigational device.

(Part 820) (subparts - A - B - C - d - e - F - g - H - i - J - K - L - M - N - O) of 21 C.F.R Quality Systems Regulation. (820 subparts) are intended to ensure that Finished devices are safe and effective.

(Part 888) of 21 C F.R 888.3300 Hip Joint metal constrained cemented or (888.3027 uncemented Prosthesis (a) Identification (b) classification. class-3 _This device is not intended For biological Fixation.

▷Cross Referenced.

(chapter-3) subparts a - b - c - d - e - F - g - h. and I-1, of 21 C.F.R (sections 301) (331) Prohibited Acts and Penalties. under Provisions of (section 404) and (sec. 721) Misleading or Falsly representing without Proper authority.