monocular glaucoma, lens rupture) have been reported. The risks of damage to the corneal endothelium, the lens, and the retina are slight. The Panel believes these risks can be kept minimal by ensuring proper device design of laser beam accuracy and precision.

FDA considered the Panel's recommendations and tentatively agreed that the generic type of device, Nd:YAG laser for peripheral iridotomy, be reclassified from class III to class II. FDA recommended that the generic designation of the device be changed from Nd:YAG laser for posterior capsulotomy to ND:YAG laser for posterior capsulotomy and peripheral iridotomy.

Subsequently, in the **Federal Register** of March 8, 1996 (61 FR 9373), FDA issued the Panel's recommendation for public comment.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation, FDA, based on its and the Panel's review, issued an order to the petitioner on August 13, 1999, reclassifying the Nd:YAG laser for posterior capsulotomy, and substantially equivalent devices of this generic type, from class III to class II, with design parameters as the special controls. Additionally, FDA changed the generic designation of the device from Nd:YAG laser for posterior capsulotomy to Nd:YAG laser for posterior capsulotomy and peripheral iridotomy. FDA believes the risks mentioned above can be kept minimal by ensuring proper device design of the laser beam accuracy and precision, and through proper device labeling disclosures whereby the surgeon can control the risk of intraocular pressure rise through available, established medical treatments.

Accordingly, as required by § 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the generic Nd:YAG laser for posterior capsulotomy and peripheral iridotomy from class III into class II. In addition, FDA is issuing the notice to codify the reclassification of the device by revising 21 CFR 886.4392.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The Commissioner of Food and Drugs therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this notice will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 886.4392 is revised to read as follows:

§ 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.

(a) *Identification.* The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

(b) *Classification.* Class II (special controls). Design Parameters: Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 micros; pulse width = 3 to 30 nanoseconds; output energy per pulse = 0.5 to 15 millijoules (mJ); repetition rate = 1 to 10 pulses; and total energy = 20 to 120 mJ.

Dated: January 24, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–3173 Filed 2–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 505

[Army Reg. 340–21]

Privacy Act; Implementation

AGENCY: Department of the Army, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Army is administratively amending an

existing exemption rule for a Privacy Act system of records. The Army is providing reasons from which information maintained within this system of records may be exempt. These were administratively omitted when last published.

EFFECTIVE DATE: February 11, 2000.

ADDRESSES: Privacy Act Officer, Records Management Program Division, U.S. Total Army Personnel Command, ATTN: TAPC-PDR-P, Stop C55, Ft. Belvoir, VA 22060-5576.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806-4390 or DSN 656-4390.

SUPPLEMENTARY INFORMATION: Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

List of Subjects in 32 CFR Part 505

Privacy.

1. The authority citation for 32 CFR part 505 continues to read as follows:

Authority: Pub. L. 93–579, 88 Stat. 1896 (5 U.S.C. 552a).

2. Section 505.5, is amended by revising paragraph (e)(18) as follows:

§ 505.5 Exemptions.

* * * * *

(e) Exempt Army records. * * *

(18) *System identifier:* A0025 JDIM

(i) *System name:* HQDA Correspondence and Control/Central Files System.

(ii) *Exemptions:* Documents within this system of records are generated by other elements of the Department of the Army or are received from other agencies and individuals. Because of the broad scope of the contents of this system of records, and since the introduction of documents is largely unregulatable, specific portions or documents that may require an exemption can not be predetermined. Therefore, and to the extent that such material is received and maintained, selected individual documents may be exempt.

(A) Information specifically authorized to be classified under E.O. 12958, as implemented by DoD 5200.1–R, may be exempt pursuant to 5 U.S.C. 552a(k)(1).

(B) Investigatory material compiled for law enforcement purposes may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of such information, the individual will be provided access to such information except to the extent that disclosure would reveal the identity of a confidential source.

(C) Records maintained in connection with providing protective services to the President and other individuals under 18 U.S.C. 3506, may be exempt pursuant to 5 U.S.C. 552a(k)(3).

(D) Records maintained solely for statistical research or program evaluation purposes and which are not used to make decisions on the rights, benefits, or entitlement of an individual except for census records which may be disclosed under 13 U.S.C. 8, may be exempt pursuant to 5 U.S.C. 552a(k)(4).

(E) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(F) Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service may be exempt pursuant to 5 U.S.C. 552a(k)(6), if the disclosure would compromise the objectivity or fairness of the test or examination process.

(G) Evaluation material used to determine potential for promotion in the Military Services may be exempt pursuant to 5 U.S.C. 552a(k)(7), but only to the extent that the disclosure of such material would reveal the identity of a confidential source.

(H) Portions of this system of records may be exempt pursuant to 5 U.S.C. 552a (k)(1) through (k)(7) from subsections (c)(3), (d), (e)(1), (e)(4)(G) and (H), and (f).

(iii) *Authority:* 5 U.S.C. 552a(k)(1) through (k)(7).

(iv) *Reasons:* (A) From subsection (c)(3) because the release of the disclosure accounting could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of the investigation and the fact that they are subjects of the investigation. It could permit the subject of an investigation or matter under investigation to obtain valuable information concerning the nature of that investigation which will present a serious impediment to law enforcement.

(B) From subsection (d) because access to the records contained in this system would inform the subject of an investigation of the existence of that investigation, provide the subject of the investigation with information that might enable him to avoid detection of apprehension, and would present a serious impediment to law enforcement.

(C) From subsection (e)(1) because in the course of criminal investigations information is often obtained concerning the violation of laws or civil obligations of others not relating to active case or matter. In the interest of effective law enforcement, it is necessary that this information be retained since it can aid in establishing patterns of activity and provide valuable leads for other agencies and future cases that may be brought.

(D) From subsections (e)(4)(G) and (H) because this system of records is exempt from individual access pursuant to subsections (k)(2) of the Privacy Act of 1974.

(E) From subsection (f) because this system of records has been exempted from the access provisions of subsection (d).

* * * * *

Dated: February 4, 2000.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense

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