proposed rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1301]

REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

Hearings—Burden of Proof

The Drug Enforcement Administration (DEA), after due consideration, seeks the adoption of proposed regulations relating to the registration of persons as compounders or to conduct narcotic treatment programs, as defined by 21 CFR 1301.02 (i) and (d).

On May 14, 1974, the "Narcotic Addict Treatment Act of 1974" was approved, amending the Controlled Substances Act (CSA) in order to increase the regulation of methadone and other narcotic drugs used in the treatment of narcotic addicts. DEA previously promulgated regulations directed to narcotic treatment programs relating to requirements for registration, physical security, records, order forms and the administering (but not prescribing) of narcotic drugs; 39 FR 37983–86 (October 25, 1974).

It is clear, as demonstrated within the legislative history, that Congress intended "to increase DEA's ability to deal with law enforcement aspects of diversion" arising from narcotic treatment programs. As stated in House Report 93–884, 1974 U.S. Code Cong. & Admin. News, p. 3033:

> "In order to qualify for registration the applicant must demonstrate that he can fulfill, and will observe, the medical standards of FDA and the security and diversion standards determined by DEA."

Generally, in the absence of proof that a person is the authorized holder of a registration under the CSA, the statutory burden of going forward with the evidence with respect to such registration is on the applicant for such registration, 21 U.S.C. 885(b). By regulation, this burden has been made applicable only in cases involving application to be registered to manufacture, import or export controlled substances in schedule I or II; 21 CFR § 1301.55(a) and 21 CFR 1311.53 (a). Likewise by regulation, in any other hearing for denial of a registration, the burden of proving that the requirements of the applicable statutory section are not satisfied is assigned to DEA; see 21 CFR § 1301.55(b). After close analysis of the statutory language and expressed Congressional intent, it is now DEA's position that, with reference to the process of granting or denying registration to applicants as compounders or to conduct a narcotic treatment program, the existing regulation concerning burden of proof in a hearing on the denial of such application for registration should be amended in order that it conform to the general statutory requirement. The proposed regulations do so.

It must be emphasized that registration under the CSA shall be obtained annually, 21 U.S.C. 822(a) and 823(g). A registration is not automatically renewable; see 21 CFR §§ 1301.41–1301.48. Every year, an applicant must be prepared to demonstrate continued fitness under the statute and regulations.

Therefore, pursuant to Sections 303(g) and 515(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 823(g) and 21 U.S.C. 885 (b)) and under the authority vested in the Attorney General by Sections 301 and 501(b) of the Act (21 U.S.C. 821 and 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by Section 0.100 of Title 28, Code of Federal Regulations, the Administrator proposes regulations amending Part 1301 of Title 21 of the Code of Federal Regulations as follows:

Section 1301.55 is amended by redesignating the present paragraph (b) as paragraph (c), by redesignating the present paragraph (c) as paragraph (d), and by adding a new paragraph (b), as follows:

§ 1301.55 Burden of proof.

* * * * *

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to Section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

* * * * *

All interested persons are invited to submit their comments and objections in writing regarding this proposal not later than May 13, 1976.

These comments or objections should state with particularity the issues concerning which the person desires to be heard. A person may object or comment on the proposals relating to either or both of the above amendments. Comments and objections should be submitted in quintuplicate to the DEA Federal Register Representative, Office of Chief Counsel, Drug Enforcement Administration, Room 1203, 1405 Eye Street NW., Washington, D.C. 20537.

In the event that comments or objections to these proposals raise one or more issues which the Administrator finds, in his sole discretion, to warrant a full adversary-type hearing, the Administrator shall order a public hearing in the FEDERAL REGISTER summarizing the issues to be heard and setting the time for the hearing.

Dated: April 2, 1976.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

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[21 CFR Part 1308]

APOMORPHINE

Removal From Schedule II

Apomorphine is a controlled substance in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 812(c) Schedule II (a)(1); § 1308.12(b)(1), Title 21 of the Code of Federal Regulations (CFR)).

Based upon the investigations of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to Section 201(b) of the Act (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration finds that apomorphine does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule under the Act.

Therefore, under the authority vested in the Attorney General by Section 201 (a) of the Act (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0), the Administrator hereby proposes that 21 CFR § 1308.12 (b) (1) be amended as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium and opiate, excluding naloxone, naltrexone, and apomorphine, and their respective salts, but including the following:

(1)	Raw opium	9,600
(2)	Opium extracts	9,610
(3)	Opium fluid extracts	9,620
(4)	Powdered opium	9,639
(5)	Granulated opium	9,640
(6)	Tincture of opium	9,630
(7)	Codeine	9,050
(8)	Ethylmorphine	9,190
(9)	Etorphine hydrochloride	9,059
(10)	Hydrocodone	9,193
(11)	Hydromorphone	9,150
(12)	Metopon	9,260
(13)	Morphine	9,300
(14)	Oxycodone	9,143
(15)	Oxymorphone	9,652
(16)	Thebaine	9,333

All interested persons are invited to submit their comments or objections in

writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 Eye Street NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative, and must be received on or before May 13, 1976.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail of the time and place that the hearing will be held. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting grounds for a hearing on the proposal are received within the time limitations, or all interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator, after giving considerations to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: April 2, 1976.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc.76-10091 Filed 4-7-76;8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[50 CFR Part 17]

AMERICAN ALLIGATOR

Proposed Reclassification

The Director, United States Fish and Wildlife Service, hereby issues a notice of proposed rulemaking which would reclassify the American alligator (*Alligator mississippiensis*) from its present listing as an endangered species to the status of a threatened species (as defined by the Endangered Species Act of 1973 (16 U.S.C. 1531-1543, 87 Stat. 884); hereinafter referred to as "the Act") in all of Florida and in certain coastal areas of Georgia, Louisiana, South Carolina and Texas. However, this proposed rulemaking would leave the alligator classified as "endangered" throughout the remainder of its range (except for Cameron, Vermilion and Calcasieu Parishes in Louisiana where, although the populations biologically are neither endangered nor threatened, the alligators have been listed as threatened due to their similarity in appearance to the endangered alligators (40 FR 44412-44429)). This rulemaking also would authorize limited, lethal removal of dangerous alligators to protect human lives and property and authorize controlled takings for scientific or conservation purposes in restricted areas under a cooperative agreement pursuant to § 6(c) of the Act, all to enhance long-range conservation objectives for this species as a renewable, natural wildlife resource.

BACKGROUND

In 1967, the U.S. Department of the Interior determined the American alligator to be an endangered species throughout its entire range. This determination reflected concern for alligator populations which had become drastically reduced after many years of excessive exploitation and habitat usurpation by man. Within recent years, however, alligators have increased considerably in some areas, mainly in response to intensive State and Federal protection. In 1972 and 1973, the State of Louisiana was able to allow a limited commercial hunting season on the species.

On December 28, 1973, the new Endangered Species Act (16 U.S.C. 1531-1543, 87 Stat. 884) went into effect. This Act made it a violation of Federal law to take any species listed as endangered, except under permit for scientific purposes or to enhance the propagation or survival of the species. The Act also established a new "threatened" classification, and authorized the Secretary of the Interior to issue such regulations as he deemed necessary and advisable for the conservation of such species.

On March 29, 1974, Governor Edwin Edwards of Louisiana submitted a petition to the Secretary of the Interior requesting that populations of the alligator "in the southwestern coastal marshes (Chenier Plain) in the parishes of Cameron, Vermilion, and Calcasieu of Louisiana, be removed from the Secretary of the Interior's list of threatened and endangered species; that in the south-central and southeastern coastal Louisiana marshes, the American alligator be classified as a threatened species; and that throughout the remainder of the State, the classification of the American alligator remain unchanged.

This petition, as amplified by other available information, was found by the Director to present substantial information warranting a review of the status of the alligator throughout its range. A notice to that effect was placed in the FEDERAL REGISTER on July 16, 1974 (39 FR 26050). Simultaneously, the Governors of States in which alligators are resident were notified of the review and were requested to supply data relative to the status of the species in their respective States.

This review produced evidence that the American alligator is making encouraging gains in population over much of its known historical range and that significant losses of populations have occurred only in geographically peripheral and possibly ecologically marginal areas. Population levels in parts of South Carolina, Georgia, Florida, Louisiana, and Texas are high, and, in many areas over these regions are considered to be ecologically secure. Increasing urbanization and development are resulting in more frequent human-alligator conflicts and control of certain populations is needed to avoid increased public hostility to the species. Even though actual numerical levels of alligators may be below the biotic carrying capacity in most habitats, socioeconomic factors must be considered in setting management goals to maximize public interest in, and acceptance of, coexistence with this potentially troublesome but ecologically important species.

Available data indicate that the primary threats to alligator populations in areas named above are not biotic, but rather the absence of adequate regulatory and enforcement mechanisms:

(1) to prevent malicious killing and illicit commercially-oriented killing and

(2) to control the illegal commerce in products.

Malicious killing stems to a large degree from public hostility and fear, and to some extent could be ameliorated through public education. Illegal commercial killing currently is being held at a tolerable level by rigid enforcement programs. These programs, however, are inadequate in the face of burgeoning alligator populations and increasing human-alligator conflicts. Reorientation of enforcement efforts toward effective control of commerce in parts and products of legally taken alligators would permit the initiation of practicable management programs and a realistic reappraisal of the population status of the species.

THE ORIGINAL PROPOSAL

As a result of this review, the Director found that there were sufficient data to warrant a proposed rulemaking that (1) the alligator is neither endangered nor threatened in Cameron, Vermilion, and Calcasieu Parishes, Louisiana; (2) the alligator is a threatened species in Alabama, Georgia, Louisiana (except Cameron, Vermilion, and Calcasieu Parishes), Mississippi, South Carolina, and Texas; and the alligator is an endangered species in all other parts of its range.

Accordingly, the Director proposed such a rulemaking on July 8, 1975 (40 FR 28712-28720). Despite reservations on the part of some responders with respect to the impact of a classification change on the welfare of the American alligator, and on other endangered wildlife which also may be reclassified at some future date, the sum of all responses reflected a preponderance of opinion in general support of the proposed rulemaking. It was determined to retain the alligator in the endangered status in all of its range except Cameron, Vermilion, and Calcasieu Parishes in Louisiana (40 FR 44412-44429). Alligators in those three parishes were listed as threatened, due to their similarity in appearance to the endangered alligators. The Service announced that it would re-study the distribution and density of alligator populations in the southeastern coastal areas and the problems of enforcement and administration. Based on this study, the Service would soon propose a reclassification of the endangered populations into threatened and endangered, with a