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accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If accepted for filing, the Administrator shall publish in the Federal Register general notice of this proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exemption, and, in the discretion of the Administrator, a summary of the subjects and issues involved. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice of proposed rulemaking the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rulemaking, the Administrator shall issue and publish in the Federal Register his final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the Federal Register unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

(d) The Administrator may revoke any exemption granted pursuant to section 201(g)(3)(A) of the Act (21 U.S.C. 811(g)(3)(A)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exemption which has been accepted for filing.


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Exempt Anabolic Steroid Products

(a) The Administrator, upon the recommendation of Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, preparation containing an anabolic steroid as defined in part 1300 of this chapter, which is intended for administration to a human being or animal, if, because of its concentration, preparation, formulation, or delivery system, it has no significant potential for abuse.

(b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act may file an application to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(75 FR 10679, Mar. 9, 2010)
any part of the Act, pursuant to para-
graph (a) of this section, may apply to
the Office of Diversion Control, Drug
Enforcement Administration. See the
Table of DEA Mailing Addresses in
§ 1321.01 of this chapter for the current
mailing address.

(c) An application for an exemption
under this section shall be submitted
in triplicate and contain the following
information:
  (1) The name and address of the ap-
plicant;
  (2) The name of the product;
  (3) The chemical structural formula
or description for any anabolic steroid
contained in the product;
  (4) The complete description of dos-
age and quantitative composition of
the dosage form;
  (5) A description of the delivery sys-
tem, if applicable;
  (6) The indications and conditions for
use in which species, including whether
or not this product is a prescription
drug;
  (7) Information to facilitate identi-
fication of the dosage form, such as
shape, color, coating, and scoring;
  (8) The label and labeling of the im-
mediate container and the commercial
containers, if any, of the product;
  (9) The units in which the dosage
form is ordinarily available; and
  (10) The facts which the applicant be-
lieves justify:
      (i) A determination that the product
has no significant potential for abuse and
      (ii) a granting of an exemption under
this section.

(d) Within a reasonable period of
time after the receipt of the applica-
tion for an exemption under this sec-
tion, the Administrator shall notify
the applicant of his acceptance or non-
acceptance of the application, and if
not accepted, the reason therefor. The
Administrator need not accept an ap-
plication for filing if any of the re-
quirements prescribed in paragraph (c)
of this section is lacking or is not set
forth so as to be readily understood.
The applicant may amend the applica-
tion to meet the requirements of para-
graph (c) of this section. If accepted for
filing, the Administrator will request
from the Secretary for Health and
Human Services his recommendation,
as to whether such product which con-
tains an anabolic steroid should be con-
sidered for exemption from certain por-
tions of the Controlled Substances Act.

On receipt of the recommendation of
the Secretary, the Administrator shall
make a determination as to whether
the evidence submitted or otherwise
available sufficiently establishes that
the product possesses no significant po-
tential for abuse. The Administrator
shall issue and publish in the FEDERAL
REGISTER his order on the application,
which shall include a reference to the
legal authority under which the order
is issued, and the findings of fact and
conclusions of law upon which the
order is based. This order shall specify
the date on which it will take effect.
The Administrator shall permit any in-
terested person to file written com-
ments on or objections to the order
within 60 days of the date of publica-
tion of his order in the FEDERAL REG-
ISTER. If any such comments or objec-
tions raise significant issues regarding
any finding of fact or conclusion of law
upon which the order is based, the Ad-
ministrator shall immediately suspend
the effectiveness of the order until he
may reconsider the application in light
of the comments and objections filed.
Thereafter, the Administrator shall re-
instate, revoke, or amend his original
order as he determines appropriate.

(e) The Administrator may revoke
any exemption granted pursuant to
section 1903(a) of Public Law 101–647 by
following the procedures set forth in
paragraph (d) of this section for han-
dling an application for an exemption
which has been accepted for filing.

§ 1308.34 Exempt anabolic steroid
products.
The list of compounds, mixtures, or
preparations that contain an anabolic
steroid that have been exempted by the
Administrator from application of sec-
tions 302 through 309 and 1002 through
1004 of the Act (21 U.S.C. 822–829 and
952–954) and §§ 1301.13, 1301.22, and
1301.71 through 1301.76 of this chapter
for administrative purposes only may