shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3297 is amended in the table in paragraph (e) by revising the entry for ''Chromium oxide green'' under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
Chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17, C.I. No. 77288).	For use only: 1. In polymers used in contact with food at a level not to exceed 5 percent by weight of the polymer, except as specified below. 2. In olefin polymers complying with § 177.1520 of this chapter. 3. In repeat-use rubber articles complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber articles.
* * *	* * * *

Dated: October 15, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–29562 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

Effective Date of Approval of an Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to amend its regulations establishing the effective date of approval of abbreviated new drug applications (ANDA's). The interim rule eliminates the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180 days of marketing exclusivity.

DATES: The interim rule is effective November 10, 1998. Submit written comments by February 3, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the act). The Hatch-Waxman Amendments created section 505(j) of the act (21 U.S.C. 355(j)). Section 505(j) created the current ANDA approval process, which allows lower-priced generic versions of previously approved innovator drugs to be approved and brought on the market.

Innovator drug applicants must include in their new drug application (NDA) information about patents that claim the drug product that is the subject of the NDA. FDA publishes this patent information as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.''

An ANDA applicant must include in the ANDA a patent certification described in section 505(j)(2)(A)(vii) of the act. The certification must make one of the following statements: (1) That no patent information on the drug product that is the subject of the ANDA has been submitted to FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted. This last certification is known as a ''paragraph IV certification.'' A notice of the paragraph IV certification must be provided to each owner of the patent which is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. The submission of an ANDA for a drug product that is claimed in a patent is an infringing act, if that drug product is intended to be marketed before the expiration of the patent, and may be the basis for patent litigation.

Section 505(j)(5)(B)(iv)[1] of the act provides an incentive for generic manufacturers to challenge patents that may be invalid or unenforceable by filing paragraph IV certifications, thereby inviting a patent action against them by the patent owner. Section 505(j)(5)(B)(iv) of the act states that:

> If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made

[1] Prior to the enactment of the Food and Drug Administration Modernization Act (the Modernization Act) of 1997, 180-day exclusivity was described at section 505(j)(4)(B)(iv) of the act. The Modernization Act added new provisions to section 505(j) that resulted in a renumbering of the sections.

effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA] or

(II) the date of a decision of a court[2] in [a patent infringement action] holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

This means that an ANDA applicant whose application contains a paragraph IV certification is protected from competition from subsequent generic versions of the same drug product for 180 days after either the first commercial marketing of the first ANDA applicant's drug or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed. This marketing protection is commonly known as ''180-day exclusivity'' and was created as an incentive to generic manufacturers to challenge patents that may be invalid, not infringed, or unenforceable.

In the **Federal Register** of October 3, 1994 (59 FR 50338 at 50367), FDA published the final rule for implementing the patent and marketing exclusivity provisions of the Hatch-Waxman Amendments. Section 314.107(c)(1) (21 CFR 314.107(c)(1)), the regulation implementing section 505(j)(5)(B)(iv) of the act, provides:

If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed *and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95*, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:

(i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or

(ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

(Emphasis added)

The proposal containing § 314.107(c)(1), published in the **Federal Register** of July 10, 1989 (54 FR 28872 at 28929), proposing the requirement that the first ANDA applicant submitting a paragraph IV certification be sued for patent infringement in order to obtain the 180-day exclusivity. This interpretation was believed to be most consistent with the language of the Hatch-Waxman Amendments and furthered the congressional intent to encourage challenges to patents that may be invalid or unenforceable (54 FR 28872 at 28894). In response to a comment on the proposed rule, FDA added a requirement to the final rule that the first ANDA applicant submitting a paragraph IV certification successfully defend a patent infringement suit to be entitled 180-day exclusivity. The ''successful defense'' requirement was established to eliminate ''an incentive for frivolous claims of patent invalidity or noninfringement because it would give ANDA applicants exclusivity even if the applicant was unsuccessful in defending against the patent owner's lawsuit'' (59 FR 50338 at 50353).

FDA's requirements for 180-day exclusivity have been challenged in *Inwood Laboratories, Inc.* v. *Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 Fed. 3d 712 (D.C. Cir. 1989); *Mova Pharmaceutical Corp.* v. *Shalala*, 955 F. Supp. 128 (D.D.C. 1997), and *Granutec, Inc. et al.* v. *Shalala et al.*, No. 5:97–CV–485–BO(1) (E.D.N.C. July 3, 1997). The district courts in both *Inwood* and *Mova* held that 180 days of marketing exclusivity should be granted to the first ANDA applicant who files a paragraph IV certification, regardless of whether the applicant is subsequently sued for patent infringement. Following the *Inwood* decision and the initial district court decision in *Mova*, FDA determined that it would be appropriate to acquiesce in the courts' decisions until the issue was resolved by the appellate courts.

The *Mova* decision was upheld in the U.S. Court of Appeals for the District of Columbia Circuit, *Mova Pharmaceutical Corp.* v. *Shalala* No. 97–5082, 1998 U.S. App. Lexis 7391 (D.C. Cir. Apr. 14, 1998). Following the circuit court decision, on June 1, 1998, the district court in *Mova* entered an order stating that the successful defense requirement of § 314.107(c)(1) is invalid and permanently enjoining FDA from enforcing it.

Subsequent to the district court decision in *Mova* and FDA's acquiesence, but prior to the Court of Appeals' decision, the U.S. District Court for the Eastern District of North Carolina addressed the validity of § 314.107(c)(1) in *Granutec* v. *Shalala* and, in a holding contrary to the earlier *Mova* district court decision, ordered FDA to follow its regulations in approving ANDA's for ranitidine hydrochloride. The *Granutec* decision was stayed and appealed to the U.S. Court of Appeals for the 4th Circuit, which reversed the district court's decision.

Both the U.S. Court of Appeals for the District of Columbia Circuit and the U.S. Court of Appeals for the 4th Circuit held that FDA's interpretation of section 505(j)(5)(B)(iv) as expressed in § 314.107(c)(1) is unsupported by the act. FDA has not appealed either decision. The effect of these decisions, together with the June 1, 1998, order of the district court in *Mova*, is that FDA will not enforce the ''successful defense'' provision of § 314.107(c)(1). Accordingly, FDA is instituting this rulemaking procedure to remove the ''successful defense'' provision from § 314.107(c)(1), and the related provision in § 314.107(c)(4).

Before either court of appeals' decision issued, in the **Federal Register** of November 28, 1997 (62 FR 63268), FDA published a clarification stating that FDA would apply § 314.107(c)(1) as written, including the ''successful defense'' provision. That clarification is hereby withdrawn.

In the near future, FDA will publish a proposed rule that will more extensively address the agency's interpretation of section 505(j)(5)(B)(iv) of the act in a manner consistent with the *Mova* and *Granutec* decisions. An opportunity for public comment will be provided when the document is published.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action 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 interim rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely

[2] The agency interprets the term ''court'' to refer to the court that enters final judgment from which no appeal can be or has been taken (§ 314.107(e)).

affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency believes that this interim rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim 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 that if a rule has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options to minimize the economic impact on small entities. The agency certifies that this interim rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires an agency to prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in expenditures by State, local, and tribal governments or the private sector of $100 million (adjusted annually for inflation) in any 1 year. The elimination of the ''successful defense'' provision of § 314.107(c)(1), and the related provision in § 314.107(c)(4), will not result in any significant increased expenditures by State, local, and tribal governments or the private sector. Because this interim rule will not result in an expenditure of $100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

This interim rule is intended to bring FDA's regulations into conformance with the *Granutec* and *Mova* court decisions. The agency believes that this interim rule is necessary and that it is consistent with the principles of Executive Order 12866; that it is not a significant regulatory action under that Order; that it will not have a significant economic impact on a substantial number of small entities; and that it is not likely to result in an annual expenditure in excess of $100 million.

IV. Paperwork Reduction Act of 1995

This interim rule contains no collections of information, therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Effective Date

The agency is issuing these amendments as an interim rule effective November 10, 1998. This action is being issued to remove the ''successful defense'' provision of § 314.107(c)(1), and the related provision in § 314.107(c)(4). This action is necessary because both the *Granutec* and *Mova* courts have found the ''successful defense'' provision to be without support in the act. Indeed, the *Mova* court has ordered FDA not to enforce the ''successful defense'' provision of § 314.107(c)(1). These decisions have rendered the ''successful defense'' provision, and the related provision in § 314.107(c)(4), a nullity, and FDA can find no reason to retain the provisions in its regulations. For the foregoing reasons, FDA finds, for good cause, that notice and public procedure would be impracticable, unnecessary, and contrary to the public interest; therefore, a public comment period before the establishment of this interim rule may be dispensed with under 5 U.S.C. 553(b)(B) and § 10.40(e)(1) (21 CFR 10.40(e)(1)). In addition, the Commissioner of Food and Drugs finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) for making this interim rule effective in less than 30 days.

VI. Opportunity for Public Comment

Interested persons may, on or before February 3, 1999, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. FDA will use any comments received to determine whether this interim rule should be modified or revoked. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

§ 314.107 [Amended]

2. Section 314.107 *Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act* is amended in paragraph (c)(1) by removing the phrase ''and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95'' and in paragraph (c)(4) by removing the phrase ''if sued for patent infringement''.

Dated: October 30, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29610 Filed 11–2–98; 11:57 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Hydrochloride Soluble Drench Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for use of levamisole hydrochloride soluble drench powder for use in water as an anthelmintic for cattle and sheep.

EFFECTIVE DATE: November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503–0103, filed ANADA 200–225 that provides for use of Prohibit™ (levamisole hydrochloride) soluble drench powder, in 46.8 and 544.5 gram packages, in water, as an anthelmintic for cattle and sheep. Levamisole cattle and sheep drench is used to treat infections of stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) (*Chabertia*, sheep only), and lung worms (*Dictyocaulus*). Agri Laboratories, Ltd.'s ANADA 200–225 is approved as a generic copy of the Schering–Plough Corp.'s NADA 112–051 Levasole® (levamisole) soluble drench. ANADA 200–225 is approved as