113TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to compounding drugs.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to compounding drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES IN ACT.

(a) SHORT TITLE.—This Act may be cited as the **[**"_____ Act"**]**.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 2. REGULATION OF HUMAN AND ANIMAL DRUG COMPOUNDING.

(a) CLARIFICATION OF NEW DRUG STATUS.—For purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the term ''new drug'' (as defined in section 201(p) of such Act) shall include a compounded drug.

(b) REGULATION OF HUMAN AND ANIMAL DRUG COMPOUNDING.—Section 503A (21 U.S.C. 353a) is amended to read as follows:

''SEC. 503A. HUMAN AND ANIMAL DRUG COMPOUNDING.

''(a) DEFINITIONS.—In this section:

''(1) COMPOUNDING.—The terms 'compounding' and 'compound'—

''(A) include compounding from bulk substances, admixing, and repackaging; and

''(B) do not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

''(2) COMPOUNDING MANUFACTURER.—

''(A) IN GENERAL.—The term 'compounding manufacturer' means an entity—

''(i) that compounds any sterile drug without receiving a prescription order for

such drug prior to beginning compounding, and introduces such compounded drug into interstate commerce; or

''(ii) that repackages a drug using sterile preservative-free single-dose vials or by pooling sterile drugs.

''(B) EXCLUDED ACTIVITIES.—An entity shall not be considered a compounding manufacturer if such entity—

''(i) repackages drugs in accordance with section 506F; and

''(ii) does not otherwise meet the definition of compounding manufacturer under subparagraph (A).

''(3) TRADITIONAL COMPOUNDER.—

''(A) IN GENERAL.—The term 'traditional compounder' means an entity—

''(i) wherein a drug is compounded by—

''(I) a licensed pharmacist in a State-licensed pharmacy; or

''(II) a licensed physician or licensed veterinarian, to the extent permitted under State law;

''(ii) that—

"(I) compounds a drug upon receipt of a prescription order for an identified individual patient; or

"(II) compounds a drug in limited quantities before receipt of a prescription order for an identified individual patient if such compounding is based on a history of the licensed pharmacist, licensed physician, or licensed veterinarian receiving prescription orders for the compounding of the drug, which orders have been generated solely within an established relationship between the licensed pharmacist, licensed physician, or licensed veterinarian and—

"(aa) such individual patient for whom the prescription order will be provided; or

"(bb) the licensed physician, licensed veterinarian, or other licensed practitioner who will write such prescription order; and

"(iii) that does not perform any of the activities described in clause (i) or (ii) of

paragraph (2)(A), except as provided in subparagraph (B).

''(B) EXCEPTION.—A pharmacy within a health system (as defined in section 506F) that compounds a drug and ships such drug for dispensing within such system (which may include interstate shipment) shall be considered a traditional compounder if such pharmacy otherwise meets the definition under subparagraph (A).

''(b) EXEMPTIONS FROM CERTAIN NEW DRUG REQUIREMENTS.—

''(1) DRUGS COMPOUNDED BY TRADITIONAL COMPOUNDERS.—Sections 501(a)(2)(B), 502(f)(1), 505 (in the case of a human drug), and 512 (in the case of an animal drug) shall not apply to a compounded drug if such drug—

''(A) is compounded by a traditional compounder that is in compliance with this section; and

''(B) meets the requirements of this section applicable to drugs compounded by traditional compounders.

''(2) DRUGS COMPOUNDED BY COMPOUNDING MANUFACTURERS.—Sections 502(f)(1), 505 (in the case of a human drug), and 512 (in the case of an

animal drug) shall not apply to a compounded drug if such drug—

"(A) is compounded by a compounding manufacturer—

"(i) that is not licensed as a pharmacy in any State; and

"(ii) that is in compliance with this section; and

"(B) meets the requirements of this section applicable to drugs compounded by compounding manufacturers.

"(c) DRUGS THAT MAY NOT BE COMPOUNDED.—

"(1) IN GENERAL.—In no case may the following drugs be compounded:

"(A) COMPLEX DOSAGE FORMS AND BIOLOGICS.—A drug that is a complex dosage form or biological product designated by the Secretary pursuant to paragraph (2).

"(B) MARKETED DRUGS.—A drug that is a copy of a marketed drug approved under section 505 or 512, including variations of such drug compounded from bulk substances and a drug subject to a risk evaluation and mitigation strategy approved with elements to assure safe

use pursuant to section 505–1, as applicable, except as provided in paragraph (3).

''(C) DRUGS REMOVED FOR SAFETY AND EFFICACY.—A drug that appears on a list published by the Secretary in the Federal Register of drugs that have been withdrawn or removed from the market because such drug or components of such drug have been found to be unsafe or not effective, subject to paragraph (4).

''(2) COMPLEX DOSAGE FORMS AND BIOLOGICS.—

''(A) IN GENERAL.—The Secretary may promulgate a regulation that designates drugs or categories of drugs that are complex dosage forms or biological products that may not be compounded. Such regulation—

''(i) may include the designation of drugs or categories of drugs that present demonstrable difficulties for compounding, such as extended release products, metered dose inhalers, transdermal patches, and liposomal products; and

''(ii) shall specify, for each drug included on the list, whether the prohibition

applies to the use of the drug in humans, animals, or both.

''(B) INTERIM LIST.—

''(i) IN GENERAL.—Before the effective date of the regulation promulgated under subparagraph (A), the Secretary may designate drugs that are complex dosage forms or biological products that cannot be compounded by—

''(I) publishing a notice of such drugs proposed for designation in the Federal Register;

''(II) providing a period of not less than 30 days for comment on the notice; and

''(III) publishing a notice in the Federal Register designating the drugs that are complex dosage forms and biological products that cannot be compounded.

''(ii) SUNSET.—Any notice provided under clause (i) shall cease to have force or effect on the date that is 5 years after the date of enactment of the [insert short title] or on the effective date of the final

regulation under subparagraph (A), whichever is earlier.

''(3) EXCEPTIONS REGARDING MARKETED DRUGS.—A drug that is a copy of a marketed drug approved under section 505 or 512, including variations of such drug compounded from bulk substances, may only be compounded if—

''(A) prior to beginning compounding a variation of such drug, the entity compounding the variation receives a prescription order for an identified individual patient indicating that the compounded variation produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the marketed drug approved under section 505 or 512, as applicable;

''(B) in the case of a marketed drug approved under section 505 that is subject to a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, the entity compounding the variation demonstrates to the Secretary that the entity will utilize controls that are comparable to the controls applicable under the

relevant risk evaluation and mitigation strategy; or

''(C)(i) such marketed drug approved under section 505 or 512 is included, at the time of compounding a copy of such drug and at the time of distribution of the compounded drug—

''(I) in the case of a human drug, on the drug shortage list under section 506E; or

''(II) in the case of an animal drug, on the Current Drug Shortages list for veterinary products maintained on the Internet Web site of the Food and Drug Administration; and

''(ii) the traditional compounder or the compounding manufacturer notifies the Secretary prior to the date that the compounding of such a drug begins.

''(4) REQUIREMENT REGARDING DRUGS REMOVED FOR SAFETY OR EFFICACY.—The list published by the Secretary in the Federal Register of drugs that have been withdrawn or removed from the market, as described in paragraph (1)(C), shall specify whether a human drug on such list may, not-

withstanding the inclusion on such list, be compounded for use in animals.

''(d) REQUIREMENTS REGARDING BULK SUBSTANCES APPLICABLE TO TRADITIONAL COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—

''(1) BULK SUBSTANCES; HUMAN DRUGS.—If a traditional compounder or a compounding manufacturer compounds a human drug using bulk substances, such compounder shall—

''(A) use bulk drug substances (as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulations))—

''(i) that—

''(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

''(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

"(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary;

"(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; and

"(B) use ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding.

"(2) BULK SUBSTANCES; ANIMAL DRUGS.—If a traditional compounder or a compounding manufacturer compounds an animal drug using bulk substances, such compounder—

"(A) shall use bulk drug substances (as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulations)) that—

"(i) are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i));

"(ii) are accompanied by valid certificates of analysis for each bulk drug substance; and

"(iii) are compounded—

"(I) using adequate procedures and processes that ensure the safety and effectiveness of the compounded drug;

"(II) using a compounding operation that is commensurate with the established need for compounded products; and

"(III) following applicable State laws relating to the compounding of drugs for use in animals;

"(B) shall use ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

"(C) in the case of a compounded animal drug for use in minor species, shall use bulk substances that—

"(i) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

"(ii) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

"(iii) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary; and

''(D) in the case of a compounded animal drug for use in major species and in food-producing animals, shall use bulk substances that are included on a list established by the Secretary of bulk substances acceptable for use in compounding a drug for one or both types of animals.

''(3) PROCEDURE.—In establishing a list of designated bulk substances acceptable for use in compounding a drug for use in major species or food-producing animals (or both) under paragraph (2)(D), the Secretary shall—

''(A) publish a notice of such bulk substances proposed for designation in the Federal Register;

''(B) provide a period of not less than 30 days for comment on the notice; and

''(C) publish a notice in the Federal Register designating the bulk substances acceptable for use in compounding a drug for use in major species or food-producing animals (or both).

''(4) WITHDRAWAL PERIODS.—The extended withdrawal periods established by the Secretary pursuant to section 530.20 of title 21, Code of Federal Regulations (or any successor regulations) shall

apply to compounded animal drugs for use in food-producing animals that were compounded using bulk substances.

''(5) IDENTIFICATION BY SECRETARY.—

''(A) IN GENERAL.—Notwithstanding the existence of an applicable monograph under paragraph (1)(A)(i)(I) or (2)(B)(i)(I), the Secretary may identify bulk substances that the Secretary determines may not be used in compounding a drug.

''(B) PROCEDURE.—In identifying the bulk substances that may not be used in compounding, the Secretary shall—

''(i) publish a notice of such bulk substances proposed for identification in the Federal Register;

''(ii) provide a period of not less than 30 days for comment on the notice; and

''(iii) publish a notice in the Federal Register identifying the bulk substances that may not be used in compounding a drug.

''(e) REQUIREMENTS REGARDING WHOLESALING AND LABELING APPLICABLE TO TRADITIONAL

COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—A compounded drug—

"(1) may not be sold by an entity other than the compounding manufacturer or traditional compounder that compounded the drug;

"(2) may not be sold to an entity other than a health care entity that provides medical services through licensed prescribers directly to patients, or a network of such providers, except that—

"(A) in the case of a drug compounded by a traditional compounder, the drug may be dispensed to an individual; and

"(B) a compounding manufacturer may transfer without profit a compounded drug to a licensed pharmacy if the licensed pharmacy falls under the same corporate ownership as the compounding manufacturer, and the transfer of such compounded drug is solely for the purpose of dispensing the compounded drug to the end user, who has been instructed by the prescribing physician to self-administer such compounded drug; and

"(3) in the case of a compounded drug sold to a health care entity described in paragraph (2), shall be labeled 'not for resale'.

''(f) OTHER REQUIREMENTS APPLICABLE TO COMPOUNDING MANUFACTURERS.—

''(1) LICENSED PHARMACIST OVERSIGHT.—A compounding manufacturer shall ensure that a pharmacist licensed in the State where the compounding manufacturer is located exercises direct supervision over the operations of the compounding manufacturer.

''(2) LISTING OF DRUGS.—

''(A) IN GENERAL.—Not less than once every 6 months, a compounding manufacturer shall file with the Secretary a list of—

''(i) the drugs compounded by such compounding manufacturer during the previous 6-month period; and

''(ii) with respect to each drug listed under clause (i), provide the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, the National Drug Code number of the final product,

and other applicable requirements identified by the Secretary in accordance with subparagraph (B).

"(B) FORM.—Each list under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

"(3) ADVERSE EVENT REPORTING.—

"(A) IN GENERAL.—If a compounding manufacturer becomes aware of any serious adverse drug experience, as defined in section 505–1(b), such manufacturer shall report each such instance to the Secretary in accordance with section 314.80(c) of title 21, Code of Federal Regulations (or any successor regulation), as soon as practicable, but in no case later than 15 calendar days after the initial receipt of the applicable information.

"(B) MAINTENANCE OF RECORDS.—A compounding manufacturer shall maintain for a period of 10 years records of all serious adverse drug experiences known to the compound manufacturer in accordance with section 314.80(i) of title 21, Code of Federal Regulations (or any

successor regulation), or as otherwise directed by the Secretary in regulations.

''(4) LABELING OF DRUGS.—The labeling of a drug compounded by a compounding manufacturer shall include—

''(A) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that identifies the drug as a compounded drug;

''(B) the name, address, and phone number of the applicable compounding manufacturer;

''(C) with respect to the compounded drug—

''(i) the lot or batch number;

''(ii) the established name of the medication;

''(iii) the strength;

''(iv) the statement of quantity;

''(v) the directions for use, as appropriate;

''(vi) the date that the drug was compounded;

''(vii) the 'beyond use' date; and

''(viii) storage instructions; and

"(D) any other information as determined necessary and specified in regulations promulgated by the Secretary.

"(g) COMPOUNDING MANUFACTURER ESTABLISHMENT AND REINSPECTION FEES.—

"(1) DEFINITIONS.—In this subsection—

"(A) the term 'affiliate' has the meaning given such term in section 735(11);

"(B) the term 'reinspection' means, with respect to a compounding manufacturer, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

"(C) the term 'reinspection-related costs' means all expenses, including administrative expenses, incurred in connection with—

"(i) arranging, conducting, and evaluating the results of reinspections; and

"(ii) assessing and collecting reinspection fees under this subsection.

''(2) ESTABLISHMENT AND REINSPECTION FEES.—For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

''(A) an establishment fee from each compounding manufacturer to cover inspection-related costs relating to inspections of drug compounders for such year; and

''(B) a reinspection fee from each compounding manufacturer subject to a reinspection in such fiscal year, to cover the reinspection-related costs associated with such compounding manufacturer for such year.

''(3) ESTABLISHMENT FEE SETTING.—The Secretary shall establish the establishment fee to be collected under this subsection for each fiscal year, based on the methodology described in paragraph (4) and shall publish such fee in a Federal Register notice not later than 60 days before the start of each such year.

''(4) AMOUNT OF ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (D), the amount of the establishment fee under paragraph (2)(A) for a

compounding manufacturer in a fiscal year shall be equal to the sum of—

"(i)(I) $15,000 per drug establishment owned or operated by the compounding manufacturer, multiplied by

"(II) the inflation adjustment factor described in subparagraph (B); plus

"(ii) the small business adjustment factor described in subparagraph (C).

"(B) INFLATION ADJUSTMENT FACTOR.—

"(i) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the revenues established in subparagraph (A) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

"(I) one;

"(II) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years,

multiplied by the proportion of personnel compensation and benefits costs to total costs of conducting inspections of drug compounders for the first 3 years of the preceding 4 fiscal years, and

''(III) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of conducting inspections of drug compounders for the first 3 years of the preceding 4 fiscal years.

''(ii) COMPOUNDED BASIS.—The adjustment made each fiscal year under clause (i) shall be added on a compounded basis to the sum of all adjustments made

each fiscal year after fiscal year 2014 under clause (i).

''(C) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor described in subparagraph (A)(ii) shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

''(i) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

''(ii) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in subparagraph (D).

''(D) EXCEPTION FOR SMALL BUSINESSES.—In the case of a compounding manufacturer that employs 25 or less employees, including employees of an affiliate, the amount of the establishment fee under paragraph (2)(A) for a fiscal year shall be equal to ⅓ of the amount calculated under subparagraph (A)(i) in such fiscal year.

''(E) CREDITING OF FEES.—In establishing the small business adjustment factor under this paragraph for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

''(5) AMOUNT OF REINSPECTION FEE.—The amount of the reinspection fee under paragraph (2)(B) for a compounding manufacturer in a fiscal year shall be the amount that is 100 percent of the reinspection-related costs (including by type or level of reinspection activity, as the Secretary determines applicable) applicable to such compounding manufacturer in such year.

''(6) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to subparagraph (A) and (B) of paragraph (2) available solely to pay for the costs referred to in such subparagraph (A) or (B) of paragraph (2), respectively.

''(7) SUPPLEMENT NOT SUPPLANT.—Funds received by the Secretary pursuant to this section shall

be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

''(8) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this subsection shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities with respect to the oversight of compounded drugs.

''(9) COLLECTION OF FEES.—

''(A) ESTABLISHMENT FEE.—A compounding manufacturer shall remit the establishment fee due under this subsection in a fiscal year when submitting a registration pursuant to section 510(g) for such fiscal year. A compounding manufacturer shall not be consid-

ered registered under section 510 in a fiscal year until the date that the compounding manufacturer remits the establishment fee under this subsection for such fiscal year.

''(B) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in paragraph (3) the time and manner in which reinspection fees assessed under this subsection shall be collected. Such a fee shall be collected after the Secretary has conducted a reinspection of the compounding manufacturer involved.

''(C) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this subsection within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

''(10) ANNUAL REPORT TO CONGRESS.—Not later than 120 days after each fiscal year in which fees are assessed under this subsection, the Secretary shall submit a report to the Committee on Health Education Labor and Pensions of the Senate and the Committee on Energy and Commerce of the

House of Representatives, to include a description of fees assessed and collected for each year, a summary description of entities paying the fees, and the number of inspections and reinspections of such entities performed each year.

''(11) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2015 and each subsequent fiscal year, there is authorized to be appropriated for fees under this subsection an amount equal to the total revenue amount estimated by the Secretary to be collected pursuant to paragraphs (4) and (5) for the fiscal year, as adjusted or otherwise affected under the other provisions of this subsection.

''(h) ACTION BY SECRETARY REGARDING COMPLAINTS FROM STATE BOARDS OF PHARMACY.—The Secretary shall encourage direct communication between States regarding traditional compounders. If the Secretary receives a complaint from a State Board of Pharmacy, in a manner specified by the Secretary, about compounded drugs produced by an identified traditional compounder licensed as a pharmacy in another identified State, the Secretary shall notify the identified State in which the traditional compounder is licensed of the complaint within 15 days. This obligation of the Secretary does not expand the

Secretary's authority over or responsibility for the traditional compounder that is the subject of the complaint.

''(i) PRESCRIPTION ORDER REFERENCE.—For purposes of this section, reference to a prescription order for an identified individual patient includes, in the case of animal drugs, a prescription order for a specific herd or flock of animals.

''(j) APPLICATION.—This section shall not apply to compounded positron emission tomography drugs.''.

(c) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(ccc) The resale of a compounded drug that is labeled 'not for resale' as required by section 503A.''.

(d) REPORT BY GAO.—Not later than November 1, 2016, the Comptroller General of the United States shall conduct study and submit to Congress a report regarding the impact of this Act (and the amendments made by this Act) on the safety of animal drug compounding and the availability of safe and effective drugs for animals.

SEC. 3. OTHER REQUIREMENTS RELATING TO COMPOUNDING MANUFACTURERS.

(a) LABELING.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(bb) If it is a compounded drug and the labeling does not include the information as required by subsections (e)(3) and (f)(4) of section 503A, as applicable.''.

(b) APPLICATION OF MANUFACTURER REGISTRATION REQUIREMENTS TO COMPOUNDING MANUFACTURERS.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraphs (1) through (5) as paragraphs (A) through (E);

(2) by striking ''(g) The foregoing'' and inserting ''(g)(1) The foregoing''; and

(3) by inserting after subparagraph (E), as so redesignated, the following:

''(2)(A) The exemption in paragraph (1)(A) does not apply with respect to compounding manufacturers. The Secretary shall establish procedures to provide for the registration under this section of compounding manufacturers, which shall include the payment of the establishment fee under section 503A(f). As part of these procedures, the Secretary shall establish a timeline for registration for the first year following the date of enactment of the [insert short title]. In no case may registration be required until at least 60 days following publication of the timeline in the Federal Register, notwithstanding subsection (b)(1).

''(B) In this subsection, the term 'compounding manufacturer' has the meaning given such term in section 503A.''.

(c) APPLICATION OF INSPECTION REQUIREMENTS TO COMPOUNDING MANUFACTURERS.—Section 704(a)(2) (21 U.S.C. 374(a)(2)) is amended by adding at the end the following flush text:

''The exemption in subparagraph (A) does not apply with respect to compounding manufacturers (as such term is defined in section 503A).''.

SEC. 4. IMPLEMENTATION.

In promulgating any regulations to implement this Act (and the amendments made by this Act), the Secretary of Health and Human Services shall—

(1) issue a notice of proposed rulemaking that includes the proposed regulation;

(2) provide a period of not less than 60 days for comments on the proposed regulation; and

(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 days before the effective date of such final regulation.