

113TH CONGRESS  
1ST SESSION

# S. 959

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

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IN THE SENATE OF THE UNITED STATES

MAY 15, 2013

Mr. HARKIN (for himself, Mr. ALEXANDER, Mr. ROBERTS, Mr. FRANKEN, and  
Ms. MIKULSKI) introduced the following bill; which was read twice and  
referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCES IN ACT.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Pharmaceutical Compounding Quality and Account-  
6 ability Act”.

7 (b) **REFERENCES IN ACT.**—Except as otherwise spec-  
8 ified, amendments made by this Act to a section or other  
9 provision of law are amendments to such section or other

1 provision of the Federal Food, Drug, and Cosmetic Act  
2 (21 U.S.C. 301 et seq.).

3 **SEC. 2. REGULATION OF HUMAN AND ANIMAL DRUG**  
4 **COMPOUNDING.**

5 (a) CLARIFICATION OF NEW DRUG AND NEW ANI-  
6 MAL DRUG STATUS.—For purposes of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the  
8 terms “new drug” (as defined in section 201(p) of such  
9 Act) and “new animal drug” (as defined in section 201(v)  
10 of such Act) shall include a compounded human drug and  
11 a compounded animal drug, respectively.

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

15 **“SEC. 503A. HUMAN AND ANIMAL DRUG COMPOUNDING.**

16 “(a) SCOPE.—

17 “(1) COMPOUNDING.—In this section, the terms  
18 ‘compounding’ and ‘compound’—

19 “(A) include—

20 “(i) the combining, admixing, mixing,  
21 diluting, reconstituting, or otherwise alter-  
22 ing of a marketed drug;

23 “(ii) compounding a drug from a bulk  
24 drug substance; and

1                   “(iii) repackaging, as defined in sub-  
2                   section (b)(5); and

3                   “(B) exclude mixing, reconstituting, or  
4                   other such acts with respect to a marketed drug  
5                   that are limited to and performed solely in ac-  
6                   cordance with specific directions for such acts  
7                   contained in approved labeling provided by a  
8                   drug’s manufacturer, when performed upon re-  
9                   ceipt of a prescription order for an identified in-  
10                  dividual patient.

11                  “(2) DISPENSING NOT A SALE.—In this section,  
12                  the terms ‘sell’ or ‘resale’ do not include dispensing  
13                  to patients, or, in the case of animal drugs, to the  
14                  individual responsible for providing care for the ani-  
15                  mal for which the drug is intended, in accordance  
16                  with State law, including any fee associated with  
17                  such dispensing.

18                  “(3) EXEMPTIONS.—This section shall not  
19                  apply to—

20                         “(A) medical gases;

21                         “(B) animal drugs that are subject to reg-  
22                         ulation as biological products by the Secretary  
23                         of Agriculture under the Act commonly known  
24                         as the Virus-Serum-Toxin Act; or

1           “(C) human blood and blood components  
2           for transfusion.

3           “(b) DEFINITIONS.—In this section:

4           “(1) COMPOUNDING MANUFACTURER.—

5           “(A) IN GENERAL.—The term  
6           ‘compounding manufacturer’ means a facility at  
7           one geographic location or address—

8           “(i) that compounds any sterile drug  
9           product without receiving a prescription  
10          order for such sterile drug product prior to  
11          beginning compounding, and distributes or  
12          offers to sell such compounded sterile drug  
13          product in interstate commerce; or

14          “(ii) that repackages any preservative-  
15          free sterile drug product or pools any ster-  
16          ile drug products, except as provided in  
17          paragraph (7)(B).

18          “(B) EXCLUDED ACTIVITIES.—Notwith-  
19          standing subparagraph (A)(ii), a facility shall  
20          not be considered a compounding manufacturer  
21          if such facility—

22          “(i) repackages drugs in accordance  
23          with section 506F or the final guidance de-  
24          scribed in section 506F(d); and

1                   “(ii) does not otherwise meet the defi-  
2                   nition of compounding manufacturer under  
3                   subparagraph (A).

4                   “(2) POOLING; POOLS.—The terms ‘pooling’  
5                   and ‘pool’—

6                   “(A) mean taking a single drug approved  
7                   under section 505 or 512, conditionally ap-  
8                   proved under section 571, included on the index  
9                   established under section 572(a)(1), or licensed  
10                  under section 351 of the Public Health Service  
11                  Act from the container in which it is distributed  
12                  by the original manufacturer and combining it  
13                  with the same drug from one or more other  
14                  containers without or before further manipu-  
15                  lating the product (such as by diluting it or  
16                  mixing it with another, different drug or  
17                  drugs);

18                  “(B) do not include combining the drug  
19                  from two or more separate containers of the  
20                  same drug when a single container of the drug  
21                  is not sufficient to prepare a single dose for ad-  
22                  ministration to an individual patient; and

23                  “(C) do not include combining the drug  
24                  from two or more separate containers of compo-  
25                  nent products of a total parenteral nutrition

1 product, if such pooling, and labeling and use  
2 of the finished total parenteral nutrition prod-  
3 uct, comply with State pharmacy law.

4 “(3) PRACTITIONER.—The term ‘practitioner’  
5 includes a physician, veterinarian, or any other per-  
6 son that is authorized to prescribe medication under  
7 State law.

8 “(4) PRESCRIPTION; PRESCRIPTION ORDER.—  
9 The term ‘prescription’ or ‘prescription order’ means  
10 a prescription or prescription order, as defined  
11 under applicable State law, that complies with re-  
12 quirements applicable under such State law.

13 “(5) REPACKAGE OR REPACKAGING.—The term  
14 ‘repackage’ or ‘repackaging’ means taking a drug  
15 approved under section 505 or 512, conditionally ap-  
16 proved under section 571, included on the index es-  
17 tablished under section 572(a)(1), or licensed under  
18 section 351 of the Public Health Service Act from  
19 the container in which it is distributed by the origi-  
20 nal manufacturer and placing it in a different con-  
21 tainer of the same or smaller size without further  
22 manipulating the drug (such as by diluting it or  
23 mixing it with another, different drug or drugs), un-  
24 less such repackaging is done pursuant to a pre-  
25 scription for an identified individual patient.

1           “(6) STERILE DRUG PRODUCT.—The term  
2           ‘sterile drug product’ means a drug that is—

3                   “(A) intended for parenteral administra-  
4           tion;

5                   “(B) an ophthalmic or inhalation drug; or

6                   “(C) required to be sterile under Federal  
7           or State law.

8           “(7) TRADITIONAL COMPOUNDER.—

9                   “(A) IN GENERAL.—The term ‘traditional  
10           compounder’ means an entity—

11                           “(i) wherein a drug is compounded  
12           by—

13                                   “(I) a licensed pharmacist, or  
14                                   other pharmacy personnel (to the ex-  
15                                   tent permitted under State law), in a  
16                                   State-licensed pharmacy or a Federal  
17                                   facility; or

18                                   “(II) a licensed physician or li-  
19                                   censed veterinarian, to the extent per-  
20                                   mitted under State law;

21                           “(ii) that—

22                                   “(I) compounds a drug upon re-  
23                                   ceipt of a prescription order for an  
24                                   identified individual patient; or

1           “(II) compounds a drug in lim-  
2           ited quantities before receipt of a pre-  
3           scription order for an identified indi-  
4           vidual patient, to the extent permitted  
5           under State law, if such compounding  
6           is based on a history of the licensed  
7           pharmacist, licensed physician, or li-  
8           censed veterinarian receiving prescrip-  
9           tion orders for the compounding of  
10          the drug, which orders have been gen-  
11          erated solely within an established re-  
12          lationship between the licensed phar-  
13          macist, licensed physician, or licensed  
14          veterinarian and—

15                 “(aa) such individual patient  
16                 for whom the prescription order  
17                 will be provided, or, in the case  
18                 of an animal drug, such indi-  
19                 vidual responsible for providing  
20                 care for the animal for which the  
21                 drug is ordered; or

22                 “(bb) the licensed physician,  
23                 licensed veterinarian, or other li-  
24                 censed practitioner who will write  
25                 such prescription order; and



1 “(iii) that does not meet the definition  
2 of a compounding manufacturer under  
3 paragraph (1).

4 “(B) EXCEPTIONS.—

5 “(i) HOSPITALS AND HEALTH SYS-  
6 TEMS.—

7 “(I) IN GENERAL.—A pharmacy  
8 within a hospital, veterinary hospital,  
9 or health system that compounds a  
10 drug and dispenses such drug (which  
11 may include interstate shipment)  
12 within such hospital or health system  
13 or ships such drug for dispensing to  
14 patients with an established relation-  
15 ship with the hospital or health sys-  
16 tem (which may include interstate  
17 shipment), or that repackages preserv-  
18 ative-free sterile drug product or pools  
19 sterile drug products, shall be consid-  
20 ered a traditional compounder if such  
21 pharmacy otherwise meets the defini-  
22 tion under subparagraph (A).

23 “(II) HEALTH SYSTEM DE-  
24 FINED.—For purposes of this sub-  
25 paragraph, the term ‘health system’

1 means two or more hospitals or veteri-  
2 nary hospitals that are owned and op-  
3 erated by the same entity and that  
4 share access to databases with drug  
5 order information for patients or ani-  
6 mals, as applicable. A health system  
7 includes both the inpatient and out-  
8 patient facilities of hospitals within  
9 the health system.

10 “(ii) PET AND RADIOPHARMA-  
11 CEUTICALS.—A pharmacy that compounds  
12 positron emission tomography drugs or  
13 radiopharmaceuticals shall be considered a  
14 traditional compounder if it does not com-  
15 pound other drugs that would cause it to  
16 be a compounding manufacturer described  
17 in paragraph (1)(A).

18 “(c) EXEMPTIONS FROM CERTAIN REQUIRE-  
19 MENTS.—

20 “(1) DRUGS COMPOUNDED BY TRADITIONAL  
21 COMPOUNDERS.—Sections 501(a)(2)(B), 502(f)(1),  
22 505 (in the case of a human drug), section 512 (in  
23 the case of an animal drug), and section 351 of the  
24 Public Health Service Act (in the case of a biological

1 product) shall not apply to a compounded drug if  
2 such drug—

3 “(A) is compounded by a traditional  
4 compounder that is in compliance with this sec-  
5 tion; and

6 “(B) meets the requirements of this sec-  
7 tion applicable to drugs compounded by tradi-  
8 tional compounders.

9 “(2) DRUGS COMPOUNDED BY COMPOUNDING  
10 MANUFACTURERS.—Sections 502(f)(1), 505 (in the  
11 case of a human drug), section 512 (in the case of  
12 an animal drug), and section 351 of the Public  
13 Health Service Act (in the case of a biological prod-  
14 uct) shall not apply to a compounded prescription  
15 drug if such drug—

16 “(A) is compounded by a compounding  
17 manufacturer—

18 “(i) that is not licensed as a phar-  
19 macy in any State; and

20 “(ii) that is in compliance with this  
21 section; and

22 “(B) meets the requirements of this sec-  
23 tion applicable to drugs compounded by  
24 compounding manufacturers.

25 “(d) DRUGS THAT MAY NOT BE COMPOUNDED.—

1           “(1) IN GENERAL.—The following drugs may  
2 not be compounded, except under conditions speci-  
3 fied by the Secretary:

4           “(A) DRUGS THAT ARE DEMONSTRABLY  
5 DIFFICULT TO COMPOUND.—A drug or category  
6 of drugs that presents demonstrable difficulties  
7 for compounding, which may include a complex  
8 dosage form or biological product, as designated  
9 by the Secretary pursuant to paragraph (2).

10           “(B) MARKETED DRUGS.—A drug, other  
11 than a biological product, that is a copy of a  
12 marketed drug approved under 505 or 512,  
13 conditionally approved under section 571, or in-  
14 cluded on the index established under section  
15 572(a)(1), except as provided in paragraph (3).

16           “(C) BIOLOGICAL PRODUCTS.—A drug  
17 that is a biological product, except as provided  
18 in paragraph (4).

19           “(D) DRUGS REMOVED FOR SAFETY AND  
20 EFFICACY.—A drug that appears on a list pub-  
21 lished by the Secretary in the Federal Register  
22 of drugs that have been withdrawn or removed  
23 from the market because such drug or compo-  
24 nents of such drug have been found to be un-  
25 safe or not effective, subject to paragraph (5).

1           “(2) DRUGS THAT ARE DEMONSTRABLY DIF-  
2           FICULT TO COMPOUND.—

3           “(A) IN GENERAL.—The Secretary may  
4           promulgate a regulation that designates drugs  
5           or categories of drugs that are demonstrably  
6           difficult to compound that may not be com-  
7           pounded, or that may be compounded only  
8           under conditions specified by the Secretary.  
9           Such regulation—

10           “(i) may include the designation of  
11           drugs or categories of drugs that are com-  
12           plex dosage forms or biological products,  
13           such as extended release products, metered  
14           dose inhalers, transdermal patches, and  
15           sterile liposomal products; and

16           “(ii) shall specify, for each drug in-  
17           cluded on the list, whether the prohibition  
18           or condition applies to the use of the drug  
19           in humans, animals, or both.

20           “(B) INTERIM LIST.—

21           “(i) IN GENERAL.—Before the effec-  
22           tive date of the regulation promulgated  
23           under subparagraph (A), the Secretary  
24           may designate drugs that are complex dos-

1 age forms or biological products that can-  
2 not be compounded by—

3 “(I) publishing a notice of such  
4 drugs proposed for designation, in-  
5 cluding the rationale for such designa-  
6 tion, in the Federal Register;

7 “(II) providing a period of not  
8 less than 60 days for comment on the  
9 notice; and

10 “(III) publishing a notice in the  
11 Federal Register designating the  
12 drugs that are complex dosage forms  
13 and biological products that cannot be  
14 compounded.

15 “(ii) SUNSET.—Any notice provided  
16 under clause (i) shall cease to have force or  
17 effect on the date that is 5 years after the  
18 date of enactment of the Pharmaceutical  
19 Compounding Quality and Accountability  
20 Act or on the effective date of the final  
21 regulation under subparagraph (A), which-  
22 ever is earlier.

23 “(3) EXCEPTIONS REGARDING MARKETED  
24 DRUGS.—

1           “(A) IN GENERAL.—A drug (other than a  
2 biological product) that is a copy of a marketed  
3 drug approved under 505 or 512, conditionally  
4 approved under section 571, or included on the  
5 index established under section 572(a)(1), in-  
6 cluding variations of such drug compounded  
7 from bulk substances, may be compounded only  
8 if—

9           “(i)(I) the compounded variation pro-  
10 duces for the patient a clinical difference  
11 between the compounded drug and such  
12 marketed drug, as determined by the pre-  
13 scribing practitioner, and, prior to begin-  
14 ning compounding a variation of such  
15 drug, the facility compounding the vari-  
16 ation receives a prescription order speci-  
17 fying that the variation may be com-  
18 pounded; or

19           “(II)(aa) such marketed drug, at the  
20 time of compounding a copy of such drug  
21 and at the time of distribution of the com-  
22 pounded drug, is on the drug shortage list  
23 under section 506E (in the case of a  
24 human drug), on the Current Drug Short-  
25 ages list for veterinary products main-

1           tained on the Internet Web site of the  
2           Food and Drug Administration (in the  
3           case of an animal drug), or in the Sec-  
4           retary’s sole discretion, has otherwise been  
5           identified by the Secretary as in shortage  
6           such as in a specific region or on a drug  
7           shortage list maintained by a private  
8           party; and

9           “(bb) the traditional compounder or  
10          the compounding manufacturer notifies the  
11          Secretary not later than 3 calendar days  
12          after beginning the compounding, unless  
13          the Secretary waives the notice require-  
14          ment; and

15          “(ii) in the case of a marketed drug  
16          approved under section 505 that is subject  
17          to a risk evaluation and mitigation strat-  
18          egy approved with elements to assure safe  
19          use pursuant to section 505–1, the entity  
20          compounding the drug demonstrates to the  
21          Secretary that the entity will utilize con-  
22          trols that are comparable to the controls  
23          applicable under the relevant risk evalua-  
24          tion and mitigation strategy.



1           “(B) EXCLUSION.—For purposes of this  
2 paragraph, repackaging a marketed drug ap-  
3 proved under section 505, 512, conditionally ap-  
4 proved under section 571, or included on the  
5 index established under section 572(a)(1), does  
6 not make the repackaged drug a copy of such  
7 marketed drug.

8           “(4) EXCEPTIONS REGARDING BIOLOGICAL  
9 PRODUCTS.—A drug that is a biological product may  
10 be compounded only if—

11           “(A) such drug is compounded from a li-  
12 censed biological product and the compounding  
13 does not involve combining or mixing the li-  
14 censed biological product with—

15           “(i) a bulk drug substance; or

16           “(ii) another, different drug or drugs  
17 approved under 505 or 512, conditionally  
18 approved under section 571, included on  
19 the index established under section  
20 572(a)(1), or licensed under section 351 of  
21 the Public Health Service Act, unless the  
22 compounding is limited to the combining,  
23 mixing, or diluting of licensed allergenic  
24 products; and

1           “(B)(i) with respect to a traditional  
2           compounder, the compounded biological product  
3           produces for the patient a clinical difference be-  
4           tween the compounded drug and the licensed bi-  
5           ological product, as determined by the pre-  
6           scribing practitioner, and, prior to beginning  
7           compounding such drug, the facility  
8           compounding the variation receives a prescrip-  
9           tion order specifying that the biological product  
10          may be compounded;

11          “(ii) with respect to a compounding manu-  
12          facturer, the compounded variation biological  
13          product produces for the patient a clinical dif-  
14          ference between the compounded drug and the  
15          licensed biological product, as determined by a  
16          licensed practitioner responsible for the pa-  
17          tient’s care in a health care entity that provides  
18          medical services through licensed prescribers di-  
19          rectly to patients, and, prior to beginning  
20          compounding such drug, the compounding man-  
21          ufacturer receives a duly authorized medical  
22          order from a hospital or health system speci-  
23          fying that the biological product may be com-  
24          pounded; or

1           “(iii) the compounded biological product is  
2           an allergenic product.

3           “(5) REQUIREMENT REGARDING DRUGS RE-  
4           MOVED FOR SAFETY OR EFFICACY.—The list pub-  
5           lished by the Secretary in the Federal Register of  
6           drugs that have been withdrawn or removed from  
7           the market, as described in paragraph (1)(D), shall  
8           specify whether a human drug on such list may, not-  
9           withstanding the inclusion on such list, be com-  
10          pounded for use in animals. The Secretary shall up-  
11          date the lists described in subparagraphs (D) and  
12          (E) of subsection (e)(2), as appropriate, to conform  
13          with the list described in paragraph (1)(D).

14          “(e) QUALITY OF DRUG INGREDIENTS.—

15                 “(1) HUMAN DRUGS.—A traditional  
16                 compounder or a compounding manufacturer shall—

17                         “(A) compound a human drug using only  
18                         bulk drug substances (as defined in regulations  
19                         of the Secretary published at section  
20                         207.3(a)(4) of title 21, Code of Federal Regula-  
21                         tions (or any successor regulations))—

22                                 “(i) that—

23   “(I) comply with the standards of  
24   an applicable United States Pharma-  
25   copoeia or National Formulary mono-

1 graph, if a monograph exists and has  
2 not been identified under paragraph  
3 (6), and the United States Pharma-  
4 copoeia chapters on pharmacy  
5 compounding;

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

10 “(III) if such a monograph does  
11 not exist and the drug substance is  
12 not a component of a drug approved  
13 by the Secretary, that appear on a list  
14 developed by the Secretary through  
15 regulations issued by the Secretary;

16 “(ii) that are manufactured by an es-  
17 tablishment that is registered under sec-  
18 tion 510 (including a foreign establishment  
19 that is registered under section 510(i));  
20 and

21 “(iii) that are accompanied by valid  
22 certificates of analysis for each specific lot  
23 of bulk drug substance; and

24 “(B) use ingredients (other than bulk drug  
25 substances) that comply with the standards of

1 an applicable United States Pharmacopoeia or  
2 National Formulary monograph, if a mono-  
3 graph exists and has not been identified under  
4 paragraph (6), and with the United States  
5 Pharmacopoeia chapter on pharmacy  
6 compounding.

7 “(2) ANIMAL DRUGS.—A traditional  
8 compounder or a compounding manufacturer shall—

9 “(A) compound an animal drug using only  
10 bulk drug substances (as defined in regulations  
11 of the Secretary published at section  
12 207.3(a)(4) of title 21, Code of Federal Regula-  
13 tions (or any successor regulations)) that—

14 “(i) are manufactured by an establish-  
15 ment that is registered under section 510  
16 (including a foreign establishment that is  
17 registered under section 510(i)); and

18 “(ii) are accompanied by valid certifi-  
19 cates of analysis for each specific lot of  
20 bulk drug substance;

21 “(B) use ingredients (other than bulk drug  
22 substances) that comply with the standards of  
23 an applicable United States Pharmacopoeia or  
24 National Formulary monograph, if a mono-  
25 graph exists and has not been identified under

1 paragraph (6), and with the United States  
2 Pharmacopoeia chapters on pharmacy  
3 compounding;

4 “(C) in the case of a compounded animal  
5 drug for use in non-food-producing minor spe-  
6 cies, use bulk substances that—

7 “(i) comply with the standards of an  
8 applicable United States Pharmacopoeia or  
9 National Formulary monograph, if a  
10 monograph exists and has not been identi-  
11 fied under paragraph (6), and with the  
12 United States Pharmacopoeia chapters on  
13 pharmacy compounding;

14 “(ii) if such a monograph does not  
15 exist, are drug substances that are compo-  
16 nents of drugs approved by the Secretary;  
17 or

18 “(iii) if such a monograph does not  
19 exist and the drug substance is not a com-  
20 ponent of a drug approved by the Sec-  
21 retary, that appear on a list developed by  
22 the Secretary through regulations issued  
23 by the Secretary;

24 “(D) in the case of a compounded animal  
25 drug for use in non-food-producing major spe-

1           cies, beginning on the date of publication of the  
2           list established in accordance with paragraph  
3           (3)(A), shall use bulk substances that are in-  
4           cluded on such list, subject to paragraph  
5           (3)(C); and

6           “(E) in the case of a compounded animal  
7           drug for use in food-producing major and minor  
8           species, shall use bulk substances that are in-  
9           cluded on a list established by the Secretary of  
10          bulk substances acceptable for use in  
11          compounding a drug for one or more such spe-  
12          cies, in accordance with paragraph (4).

13          “(3) NON-FOOD-PRODUCING MAJOR SPECIES  
14          LISTING PROCEDURE.—

15          “(A) IN GENERAL.—Not later than 30  
16          days after the effective date of the Pharma-  
17          ceutical Compounding Quality and Account-  
18          ability Act, the Secretary shall establish a list  
19          of bulk substances acceptable for compounding  
20          a drug for use in non-food-producing major spe-  
21          cies, and any conditions applicable to such use,  
22          and may also identify bulk substances that the  
23          Secretary has determined not acceptable for  
24          compounding with respect to a drug for use in  
25          such species.

1           “(B) PROCEDURE.—In developing and up-  
2           dating the list under subparagraph (A), the  
3           Secretary shall—

4                   “(i) publish a notice in the Federal  
5                   Register identifying bulk substances pro-  
6                   posed as acceptable and any bulk sub-  
7                   stance determine to be unacceptable, and  
8                   the rationale for such proposed designa-  
9                   tions;

10                   “(ii) provide a period of not less than  
11                   30 days for comment on the notice; and

12                   “(iii) publish a notice in the Federal  
13                   Register designating the bulk substances  
14                   acceptable, and any bulk substances deter-  
15                   mined to be unacceptable, and the ration-  
16                   ale for such designations and determina-  
17                   tions.

18           “(C) NOTIFICATION.—Upon initial publica-  
19           tion of the list under subparagraph (B)(iii), any  
20           traditional compounder or compounding manu-  
21           facturer that has received and filled a prescrip-  
22           tion in the 60 days prior to such publication for  
23           a compounded drug for a non-food-producing  
24           major species from a bulk substance not ad-  
25           dressed in the notice (either as acceptable or



1 unacceptable), and that reasonably expect to re-  
2 ceive and fill another prescription for such a  
3 drug for such species within 60 days after such  
4 publication, may notify the Secretary of such  
5 bulk substance within 30 days of such publica-  
6 tion, in a manner to be determined by the Sec-  
7 retary and published in the Federal Register on  
8 or before publication of the list under subpara-  
9 graph (B)(iii). A traditional compounder or  
10 compounding manufacturer that provides such  
11 notice shall not be subject to the restriction in  
12 paragraph (2)(D) until such time as the Sec-  
13 retary designates such bulk substance as ac-  
14 ceptable or determines it to be unacceptable  
15 pursuant to the process described in subpara-  
16 graph (B)(iii).

17 “(D) MODIFICATION OF LIST.—The Sec-  
18 retary may amend the list at any time, in ac-  
19 cordance with process described in subpara-  
20 graph (B).

21 “(E) CRITERIA.—In evaluating bulk sub-  
22 stances for purposes of subparagraph (B), the  
23 Secretary shall consider, among other factors—

24 “(i) the safety of the bulk substance;

1                   “(ii) historical use of the substance in  
2                   pharmacy compounding;

3                   “(iii) evidence of the effectiveness of  
4                   the bulk substance or lack of effectiveness;

5                   “(iv) whether any drug approved  
6                   under section 505 or 512, conditionally ap-  
7                   proved under section 571, or included on  
8                   the index established under section  
9                   572(a)(1), can be used on label, or any  
10                  drug approved under section 505 or 512  
11                  can be used in an extralabel manner in ac-  
12                  cordance with section paragraphs (4) and  
13                  (5) of section 512(a), to treat the applica-  
14                  ble condition in the identified species; and

15                  “(v) whether a compounded drug ap-  
16                  propriate to treat the applicable condition  
17                  in the identified species could be obtained  
18                  by manipulating a drug approved under  
19                  505 or 512, conditionally approved under  
20                  section 571, or included on the index es-  
21                  tablished under section 572(a)(1).

22                  “(4) FOOD-PRODUCING ANIMALS LISTING PRO-  
23                  CEDURE.—In establishing a list of designated bulk  
24                  substances acceptable for use in compounding a  
25                  drug for use in food-producing major and minor spe-

1       cies under paragraph (2), and any conditions appli-  
2       cable to such use, the Secretary shall—

3               “(A) publish a notice in the Federal Reg-  
4       ister identifying bulk substances proposed as  
5       acceptable and any bulk substance determine to  
6       be unacceptable, and the rationale for such des-  
7       ignations;

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

10              “(C) publish a notice in the Federal Reg-  
11       ister designating the bulk substances acceptable  
12       for use in compounding a drug for use in food-  
13       producing major and minor species, and the ra-  
14       tionale for such designations.

15              “(5) WITHDRAWAL PERIODS.—The require-  
16       ments for establishing substantially extended with-  
17       drawal periods in accordance with section 530.20 of  
18       title 21, Code of Federal Regulations (or any suc-  
19       cessor regulations) shall apply to compounded ani-  
20       mal drugs for use in food-producing animals that  
21       are compounded using bulk substances.

22              “(6) IDENTIFICATION BY SECRETARY.—

23              “(A) IN GENERAL.—Notwithstanding the  
24       existence of an applicable monograph under  
25       subparagraph (A)(i)(I) or (B) of paragraph (1)

1 or subparagraph (B) or (C)(i) of paragraph (2),  
2 the Secretary may identify bulk substances that  
3 the Secretary determines, based on public  
4 health concerns, may not be used in  
5 compounding a drug.

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

9 “(i) publish a notice of such bulk sub-  
10 stances proposed for identification in the  
11 Federal Register;

12 “(ii) provide a period of not less than  
13 60 days for comment on the notice;

14 “(iii) publish a notice in the Federal  
15 Register identifying the bulk substances  
16 that may not be used in compounding a  
17 drug; and

18 “(iv) state whether the bulk is not  
19 suitable for compounding of human drugs,  
20 animal drugs, or both.

21 “(f) REQUIREMENTS REGARDING WHOLESALING  
22 AND LABELING APPLICABLE TO TRADITIONAL  
23 COMPOUNDERS AND COMPOUNDING MANUFACTURERS.—

24 “(1) IN GENERAL.—A compounded drug—

1           “(A) may not be sold by an entity other  
2 than the compounding manufacturer or tradi-  
3 tional compounder that compounded the drug;

4           “(B) compounded by a compounding man-  
5 ufacturer may not be sold to an entity other  
6 than a health care entity that provides medical  
7 services through licensed prescribers directly to  
8 patients or animals, or a network of such pro-  
9 viders, except that a compounding manufac-  
10 turer may transfer without profit a compounded  
11 sterile drug to a licensed pharmacy if—

12           “(i) the licensed pharmacy falls under  
13 the same corporate ownership as the  
14 compounding manufacturer;

15           “(ii) the transfer of such compounded  
16 sterile drug is solely for the purpose of dis-  
17 pensing the compounded sterile drug to the  
18 end user, who has been instructed by the  
19 prescribing physician to self-administer  
20 such compounded sterile drug;

21           “(iii) as of the date of enactment of  
22 the Pharmaceutical Compounding Quality  
23 and Accountability Act, the compounding  
24 manufacturer is an entity that provides

1 pharmacy benefits management services on  
2 behalf of a health benefits plan;

3 “(iv) the compounding manufacturer  
4 identifies itself to the Secretary upon reg-  
5 istering under subsection (g)(2) as an enti-  
6 ty that qualifies for the exemption under  
7 this subparagraph, and provides docu-  
8 mentation of the compounding of such  
9 drugs as of the date of enactment of the  
10 Pharmaceutical Compounding Quality and  
11 Accountability Act, in a manner described  
12 by the Secretary; and

13 “(v) the compounding manufacturer  
14 receives confirmation from the Secretary  
15 that the compounding manufacturer quali-  
16 fies for the exemption under this subpara-  
17 graph and the sterile drug or drugs for  
18 which the exemption applies; and

19 “(C) in the case of a compounded drug  
20 sold to a health care entity described in sub-  
21 paragraph (B), shall be labeled ‘not for resale’.

22 “(2) ADVERTISING AND PROMOTION.—The ad-  
23 vertising and promotion of compounded drugs shall  
24 not be false or misleading in any particular.

1       “(g) OTHER REQUIREMENTS APPLICABLE TO  
2 COMPOUNDING MANUFACTURERS.—

3           “(1) LICENSED PHARMACIST OVERSIGHT.—A  
4 compounding manufacturer shall ensure that a phar-  
5 macist licensed in the State where the compounding  
6 manufacturer is located exercises direct supervision  
7 over the operations of the compounding manufac-  
8 turer.

9           “(2) REGISTRATION OF COMPOUNDING MANU-  
10 FACTURERS AND REPORTING OF DRUGS.—

11           “(A) REGISTRATION OF COMPOUNDING  
12 MANUFACTURERS.—

13           “(i) ANNUAL REGISTRATION.—During  
14 the period beginning on October 1 and  
15 ending on December 31 each year, each  
16 compounding manufacturer shall register  
17 with the Secretary its name, place of busi-  
18 ness, and unique facility identifier (which  
19 shall conform to the requirements for the  
20 unique facility identifier established under  
21 section 510), and a point of contact e-mail  
22 address.

23           “(ii) NEW COMPOUNDING MANUFAC-  
24 TURERS.—Each compounding manufac-  
25 turer, upon first engaging in the oper-

1 ations described in subsection (b)(1), shall  
2 immediately register with the Secretary  
3 and provide the information described  
4 under clause (i). The Secretary shall estab-  
5 lish a timeline for registration for the first  
6 year following the effective date of the  
7 Pharmaceutical Compounding Quality and  
8 Accountability Act. In no case may reg-  
9 istration be required until at least 60 days  
10 following publication of the timeline in the  
11 Federal Register.

12 “(iii) ADDITIONAL FACILITIES.—Each  
13 compounding manufacturer duly registered  
14 in accordance with clauses (i) and (ii) shall  
15 immediately identify to the Secretary any  
16 additional facility that engages in the ac-  
17 tivities described in subsection (b)(1) and  
18 that is owned or operated in any State by  
19 the person that owns or operates the  
20 compounding manufacturer.

21 “(iv) AVAILABILITY OF REGISTRATION  
22 FOR INSPECTION.—The Secretary shall  
23 make available for inspection, to any per-  
24 son so requesting, any registration filed  
25 pursuant to this subparagraph, except that



1 any drug reporting information submitted  
2 pursuant to this subparagraph and the in-  
3 formation accompanying such reporting  
4 shall be exempt from such inspection, un-  
5 less the Secretary finds that such an ex-  
6 emption would be inconsistent with the  
7 protection of the public health.

8 “(B) DRUG REPORTING BY COMPOUNDING  
9 MANUFACTURERS.—

10 “(i) IN GENERAL.—Each compound-  
11 ing manufacturer who registers with the  
12 Secretary under subparagraph (A) shall  
13 submit to the Secretary, once during the  
14 month of June of each year and once dur-  
15 ing the month of December of each year,  
16 a report—

17 “(I) identifying the drugs com-  
18 pounded by such compounding manu-  
19 facturer during the previous 6-month  
20 period; and

21 “(II) with respect to each drug  
22 identified under subclause (I), pro-  
23 viding the active ingredient, the  
24 source of such active ingredient, the  
25 National Drug Code number of the

1 source drug or bulk active ingredient,  
2 the strength of the active ingredient  
3 per unit, the dosage form and route of  
4 administration, the package descrip-  
5 tion, the number of individual units  
6 produced, the National Drug Code  
7 number of the final product, and  
8 which conforms to other applicable re-  
9 quirements identified by the Secretary  
10 in accordance with clause (ii).

11 “(ii) FORM.—Each report under  
12 clause (i) shall be prepared in such form  
13 and manner as the Secretary may pre-  
14 scribe by regulation or guidance.

15 “(C) ELECTRONIC REGISTRATION AND RE-  
16 PORTING.—Registrations and drug reporting  
17 under this paragraph (including the submission  
18 of updated information) shall be submitted to  
19 the Secretary by electronic means unless the  
20 Secretary grants a request for waiver of such  
21 requirement because use of electronic means is  
22 not reasonable for the person requesting waiver.

23 “(D) RISK-BASED INSPECTION FRE-  
24 QUENCY.—

1           “(i) IN GENERAL.—Compounding  
2 manufacturers shall be subject to inspec-  
3 tion pursuant to section 704.

4           “(ii) RISK-BASED SCHEDULE.—The  
5 Secretary, acting through one or more offi-  
6 cers or employees duly designated by the  
7 Secretary, shall inspect compounding man-  
8 ufacturers described in clause (i) in accord-  
9 ance with a risk-based schedule established  
10 by the Secretary.

11           “(iii) RISK FACTORS.—In establishing  
12 the risk-based schedule under clause (ii),  
13 the Secretary shall inspect compounding  
14 manufacturers according to the known  
15 safety risks of such compounding manufac-  
16 turers, which shall be based on the fol-  
17 lowing factors:

18                   “(I) The compliance history of  
19 the compounding manufacturer.

20                   “(II) The record, history, and na-  
21 ture of recalls linked to the  
22 compounding manufacturer.

23                   “(III) The inherent risk of the  
24 drug compounded at the compounding  
25 manufacturer.

1           “(IV) The inspection frequency  
2           and history of the compounding man-  
3           ufacturer, including whether the  
4           compounding manufacturer has been  
5           inspected pursuant to section 704  
6           within the last 4 years.

7           “(V) Any other criteria deemed  
8           necessary and appropriate by the Sec-  
9           retary for purposes of allocating in-  
10          spection resources.

11          “(3) ADVERSE EVENT REPORTING.—

12           “(A) DEFINITIONS.—In this paragraph:

13           “(i) ADVERSE EVENT.—The term ‘ad-  
14           verse event’ means any health-related event  
15           associated with the use of a compounded  
16           drug that is adverse, including—

17           “(I) an event occurring in the  
18           course of the use of the drug in pro-  
19           fessional practice;

20           “(II) an event occurring from an  
21           overdose of the drug, whether acci-  
22           dental or intentional;

23           “(III) an event occurring from  
24           abuse of the drug;

1                   “(IV) an event occurring from  
2                   withdrawal of the drug; and

3                   “(V) any failure of expected  
4                   pharmacological action of the drug.

5                   “(ii) SERIOUS ADVERSE EVENT.—The  
6                   term ‘serious adverse event’ means an ad-  
7                   verse event that—

8                   “(I) results in—

9                   “(aa) death;

10                   “(bb) an adverse drug event  
11                   that places the patient at imme-  
12                   diate risk of death from the ad-  
13                   verse drug event as it occurred  
14                   (not including an adverse drug  
15                   event that might have caused  
16                   death had it occurred in a more  
17                   severe form);

18                   “(cc) inpatient hospitaliza-  
19                   tion or prolongation of existing  
20                   hospitalization;

21                   “(dd) a persistent or signifi-  
22                   cant incapacity or substantial  
23                   disruption of the ability to con-  
24                   duct normal life functions; or

1                   “(ee) a congenital anomaly  
2                   or birth defect; or

3                   “(II) based on appropriate med-  
4                   ical judgment, may jeopardize the pa-  
5                   tient and may require a medical or  
6                   surgical intervention to prevent an  
7                   outcome described in subclause (I).

8                   “(B) REPORTS.—

9                   “(i) ADVERSE EVENT REPORTING RE-  
10                  QUIREMENT.—

11                  “(I) 15-DAY REPORT.—If a  
12                  compounding manufacturer becomes  
13                  aware of any serious adverse event,  
14                  such manufacturer shall submit re-  
15                  ports of each instance to the Sec-  
16                  retary as soon as practicable, but in  
17                  no case later than 15 calendar days  
18                  after the initial receipt of the applica-  
19                  ble information. Such manufacturer  
20                  shall investigate and submit to the  
21                  Secretary followup reports for each  
22                  such instance not later than 15 cal-  
23                  endar days after receipt of new infor-  
24                  mation or as requested by the Sec-  
25                  retary. Unless and until the Secretary

1 establishes the content and format of  
2 adverse event reports by guidance or  
3 regulation, reports shall be submitted  
4 in accordance with the content and  
5 format requirements under section  
6 310.305 of title 21, Code of Federal  
7 Regulations (or any successor regula-  
8 tions) (in the case of human drugs),  
9 section 600.80 of title 21, Code of  
10 Federal Regulations (or any successor  
11 regulations) (in the case of biological  
12 products), or section 514.80 of title  
13 21, Code of Federal Regulations (or  
14 any successor regulations) (in the case  
15 of animal drugs).

16 “(II) ANNUAL REPORT.—  
17 Compounding manufacturers that re-  
18 port serious adverse events shall sub-  
19 mit in December of each year a nar-  
20 rative summary of any analysis of  
21 each report submitted under subclause  
22 (I), including a history of actions  
23 taken during the year because of each  
24 report, using the content, format, and  
25 manner established by the Secretary

1 by guidance or regulation. Until such  
2 time as the Secretary publishes such  
3 guidance or regulation, each  
4 compounding manufacturer shall re-  
5 tain such summaries as part of the  
6 records to be maintained in accord-  
7 ance with subparagraph (C).

8 “(ii) PRODUCT QUALITY REPORTING  
9 REQUIREMENT.—Not later than 3 calendar  
10 days after the compounding manufacturer  
11 becomes aware of information pertaining  
12 to sterility, stability, or other product qual-  
13 ity concerns that could result in serious  
14 adverse events, the compounding manufac-  
15 turer shall submit to the Secretary a prod-  
16 uct quality report, in a form and manner  
17 established by the Secretary by guidance or  
18 regulation.

19 “(C) MAINTENANCE OF RECORDS.—A  
20 compounding manufacturer shall maintain for a  
21 period of 10 years records of all serious adverse  
22 drug events known to the compound manufac-  
23 turer in accordance with section 314.80(i) of  
24 title 21, Code of Federal Regulations (or any



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

3 “(4) LABELING OF DRUGS.—

4 “(A) LABEL.—The label of a drug com-  
5 pounded by a compounding manufacturer shall  
6 include—

7 “(i) the statement ‘This is a com-  
8 pounded drug.’ or a reasonable comparable  
9 alternative statement (as specified by the  
10 Secretary) that identifies the drug as a  
11 compounded drug;

12 “(ii) the name, address, and phone  
13 number of the applicable compounding  
14 manufacturer; and

15 “(iii) with respect to the compounded  
16 drug—

17 “(I) the lot or batch number;

18 “(II) the established name of the  
19 medication;

20 “(III) the dosage form and  
21 strength;

22 “(IV) the statement of quantity  
23 or volume, as appropriate;

24 “(V) in the case of a drug in-  
25 tended for use in a food-producing

1 animal, the withdrawal period estab-  
2 lished pursuant to subsection (e)(5) to  
3 ensure that no residues from the com-  
4 pounded drug can be detected in edi-  
5 ble tissues of the treated animal;

6 “(VI) the date that the drug was  
7 compounded;

8 “(VII) the expiration date;

9 “(VIII) storage and handling in-  
10 structions;

11 “(IX) the National Drug Code  
12 number, if available;

13 “(X) the ‘not for resale’ state-  
14 ment required as required by sub-  
15 section (f)(1)(C); and

16 “(XI) subject to subparagraph  
17 (B)(i), a list of active and inactive in-  
18 gredients, identified by established  
19 name and the quantity or proportion  
20 of each ingredient.

21 “(B) CONTAINER.—The container from  
22 which the individual units of a drug com-  
23 pounded by a compounding manufacturer are  
24 removed for dispensing or for administration

1 (such as a plastic bag containing individual  
2 product syringes) shall include—

3 “(i) the information described under  
4 subparagraph (A)(iii)(XI), if there is not  
5 space on the label for such information;

6 “(ii) the following information to fa-  
7 cilitate adverse event reporting:  
8 [www.fda.gov/medwatch](http://www.fda.gov/medwatch) and 1-800-FDA-  
9 1088; and

10 “(iii) the directions for use, including  
11 dosage and administration, as appropriate.

12 “(C) ADDITIONAL INFORMATION.—The  
13 label and labeling of a drug compounded by a  
14 compounding manufacturer shall include any  
15 other information as determined necessary and  
16 specified in regulations promulgated by the Sec-  
17 retary.

18 “(h) COMPOUNDING MANUFACTURER ESTABLISH-  
19 MENT AND REINSPECTION FEES.—

20 “(1) DEFINITIONS.—In this subsection—

21 “(A) the term ‘affiliate’ has the meaning  
22 given such term in section 735(11);

23 “(B) the term ‘gross annual sales’ means  
24 the total worldwide gross annual sales, in  
25 United States dollars, for a compounding man-

1 manufacturer, including the sales of all the affiliates  
2 of the compounding manufacturer; and

3 “(C) the term ‘reinspection’ means, with  
4 respect to a compounding manufacturer, one or  
5 more inspections conducted under section 704  
6 subsequent to an inspection conducted under  
7 such provision which identified noncompliance  
8 materially related to an applicable requirement  
9 of this Act, specifically to determine whether  
10 compliance has been achieved to the Secretary’s  
11 satisfaction.

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

16 “(A) an annual establishment fee from  
17 each compounding manufacturer to cover in-  
18 spection-related costs relating to inspections of  
19 drug compounders for such year; and

20 “(B) a reinspection fee from each  
21 compounding manufacturer subject to a rein-  
22 spection in such fiscal year.

23 “(3) ESTABLISHMENT AND REINSPECTION FEE  
24 SETTING.—The Secretary shall establish the estab-  
25 lishment and reinspection fee to be collected under

1 this subsection for each fiscal year, based on the  
2 methodology described in paragraph (4) and shall  
3 publish such fee in a Federal Register notice not  
4 later than 60 days before the start of each such  
5 year.

6 “(4) AMOUNT OF ESTABLISHMENT AND REIN-  
7 SPECTION FEE.—

8 “(A) IN GENERAL.—Except as provided in  
9 subparagraph (D), the amount of the annual  
10 establishment fee and the reinspection fee (if  
11 applicable) under paragraph (2) for each  
12 compounding manufacturer in a fiscal year  
13 shall be equal to the sum of—

14 “(i)(I) \$15,000 per compounding  
15 manufacturer, multiplied by

16 “(II) the inflation adjustment factor  
17 described in subparagraph (B); plus

18 “(ii) the small business adjustment  
19 factor described in subparagraph (C).

20 “(B) INFLATION ADJUSTMENT FACTOR.—

21 “(i) IN GENERAL.—For fiscal year  
22 2015 and subsequent fiscal years, the reve-  
23 nues established in subparagraph (A) shall  
24 be adjusted by the Secretary by notice,  
25 published in the Federal Register, for a

1 fiscal year by the amount equal to the sum  
2 of—

3 “(I) one;

4 “(II) the average annual percent  
5 change in the cost, per full-time equiv-  
6 alent position of the Food and Drug  
7 Administration, of all personnel com-  
8 pensation and benefits paid with re-  
9 spect to such positions for the first 3  
10 years of the preceding 4 fiscal years,  
11 multiplied by the proportion of per-  
12 sonnel compensation and benefits  
13 costs to total costs of an average full-  
14 time equivalent position of the Food  
15 and Drug Administration for the first  
16 3 years of the preceding 4 fiscal  
17 years, and

18 “(III) the average annual percent  
19 change that occurred in the Consumer  
20 Price Index for urban consumers  
21 (U.S. City Average; Not Seasonally  
22 Adjusted; All items; Annual Index) for  
23 the first 3 years of the preceding 4  
24 years of available data multiplied by  
25 the proportion of all costs other than

1 personnel compensation and benefits  
2 costs to total costs of an average full-  
3 time equivalent position of the Food  
4 and Drug Administration for the first  
5 3 years of the preceding 4 fiscal  
6 years.

7 “(ii) COMPOUNDED BASIS.—The ad-  
8 justment made each fiscal year under  
9 clause (i) shall be added on a compounded  
10 basis to the sum of all adjustments made  
11 each fiscal year after fiscal year 2014  
12 under clause (i).

13 “(C) SMALL BUSINESS ADJUSTMENT FAC-  
14 TOR.—The small business adjustment factor de-  
15 scribed in subparagraph (A)(ii) shall be an  
16 amount established by the Secretary for each  
17 fiscal year based on the Secretary’s estimate  
18 of—

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

22 “(ii) the adjustment to the establish-  
23 ment fee necessary to achieve total fees  
24 equaling the total fees that the Secretary  
25 would have collected if no entity qualified

1 for the small business exception in sub-  
2 paragraph (D).

3 “(D) EXCEPTION FOR SMALL BUSI-  
4 NESSES.—

5 “(i) IN GENERAL.—In the case of a  
6 compounding manufacturer with gross an-  
7 nual sales of \$1,000,000 or less in the 12  
8 months ending June 1 of the fiscal year  
9 immediately preceding the fiscal year in  
10 which the fees under this subsection are  
11 assessed, the amount of the establishment  
12 fee and reinspection fee under paragraph  
13 (2) for a fiscal year shall be equal to  $\frac{1}{3}$  of  
14 the amount calculated under subparagraph  
15 (A)(i) in such fiscal year.

16 “(ii) APPLICATION.—The Secretary  
17 may require a small business to apply for  
18 the exception under this subparagraph by  
19 certifying its gross annual sales for the 12  
20 months ending June 1 of the fiscal year  
21 immediately preceding the fiscal year in  
22 which fees under this subsection are as-  
23 sessed. Any such application must be sub-  
24 mitted to the Secretary prior to August 1  
25 for the following fiscal year. Any statement



1 or representation made to the Secretary  
2 shall be subject to section 1001 of title 18,  
3 United States Code.

4 “(E) CREDITING OF FEES.—In estab-  
5 lishing the small business adjustment factor  
6 under subparagraph (C) for a fiscal year, the  
7 Secretary shall provide for the crediting of fees  
8 from the previous year to the next year if the  
9 Secretary overestimated the amount of the  
10 small business adjustment factor for such pre-  
11 vious fiscal year, and consider the need to ac-  
12 count for any adjustment of fees and such other  
13 factors as the Secretary determines appropriate.

14 “(5) USE OF FEES.—The Secretary shall make  
15 all of the fees collected pursuant to subparagraph  
16 (A) and (B) of paragraph (2) available solely to pay  
17 for the inspection-related costs (including re-inspec-  
18 tion) for the oversight of drug compounding.

19 “(6) SUPPLEMENT NOT SUPPLANT.—Funds re-  
20 ceived by the Secretary pursuant to this subsection  
21 shall be used to supplement and not supplant any  
22 other Federal funds available to carry out the activi-  
23 ties described in this subsection.

24 “(7) CREDITING AND AVAILABILITY OF FEES.—  
25 Fees authorized under this subsection shall be col-

1 lected and available for obligation only to the extent  
2 and in the amount provided in advance in appropria-  
3 tions Acts. Such fees are authorized to remain avail-  
4 able until expended. Such sums as may be necessary  
5 may be transferred from the Food and Drug Admin-  
6 istration salaries and expenses appropriation account  
7 without fiscal year limitation to such appropriation  
8 account for salaries and expenses with such fiscal  
9 year limitation. The sums transferred shall be avail-  
10 able solely for the purpose of paying the inspection-  
11 related costs (including reinspection) for the over-  
12 sight of drug compounding.

13 “(8) COLLECTION OF FEES.—

14 “(A) ESTABLISHMENT FEE.—A  
15 compounding manufacturer shall remit the es-  
16 tablishment fee due under this subsection in a  
17 fiscal year when submitting a registration pur-  
18 suant to subsection (g) for such fiscal year.

19 “(B) REINSPECTION FEE.—The Secretary  
20 shall specify in the Federal Register notice de-  
21 scribed in paragraph (3) the manner in which  
22 reinspection fees assessed under this subsection  
23 shall be collected and the timeline for payment  
24 of such fees. Such a fee shall be collected after

1 the Secretary has conducted a reinspection of  
2 the compounding manufacturer involved.

3 “(C) EFFECT OF FAILURE TO PAY FEES.—

4 “(i) REGISTRATION.—A compounding  
5 manufacturer shall not be considered reg-  
6 istered under subsection (g) in a fiscal year  
7 until the date that the compounding manu-  
8 facturer remits the establishment fee under  
9 this subsection for such fiscal year.

10 “(ii) MISBRANDING.—All drugs com-  
11 pounded by a compounding manufacturer  
12 for which any establishment fee or rein-  
13 spection fee has not been paid as required  
14 by this subsection shall be deemed mis-  
15 branded under section 502(cc) until the  
16 fees owed for such compounding manufac-  
17 turer under this subsection have been paid.

18 “(D) COLLECTION OF UNPAID FEES.—In  
19 any case where the Secretary does not receive  
20 payment of a fee assessed under this subsection  
21 within 30 days after it is due, such fee shall be  
22 treated as a claim of the United States Govern-  
23 ment subject to provisions of subchapter II of  
24 chapter 37 of title 31, United States Code.

1           “(9) ANNUAL REPORT TO CONGRESS.—Not  
2 later than 120 days after each fiscal year in which  
3 fees are assessed and collected under this subsection,  
4 the Secretary shall submit a report to the Com-  
5 mittee on Health, Education, Labor, and Pensions  
6 of the Senate and the Committee on Energy and  
7 Commerce of the House of Representatives, to in-  
8 clude a description of fees assessed and collected for  
9 each year, a summary description of entities paying  
10 the fees, and the number of inspections and re-  
11 inspections of such entities performed each year.

12           “(10) AUTHORIZATION OF APPROPRIATIONS.—  
13 For fiscal year 2015 and each subsequent fiscal  
14 year, there is authorized to be appropriated for fees  
15 under this subsection an amount equivalent to the  
16 total amount of fees assessed for such fiscal year  
17 under this subsection.

18           “(i) ACTION BY SECRETARY REGARDING COM-  
19 PLAINS FROM STATE BOARDS OF PHARMACY.—

20           “(1) DESIGNATION.—The Secretary shall des-  
21 ignate a point of contact and establish a format and  
22 procedure for a State Board of Pharmacy to notify  
23 the Secretary if it appears to a State Board of Phar-  
24 macy that an entity licensed by a State as a phar-

1 macy is required to be registered with the Secretary  
2 as a compounding manufacturer.

3 “(2) DETERMINATION.—If the Secretary deter-  
4 mines that such an entity described in paragraph (1)  
5 is required to be registered with the Secretary as a  
6 compounding manufacturer, the Secretary shall  
7 transmit such determination to the State Board of  
8 Pharmacy in the State in which the entity is located,  
9 and to the State Board of Pharmacy in the notifying  
10 State, if different, within 15 days of such determina-  
11 tion.

12 “(3) EFFECT.—The Secretary shall encourage  
13 direct communications between States regarding tra-  
14 ditional compounders. Nothing in this subsection  
15 shall expand the Secretary’s authority over or re-  
16 sponsibility for traditional compounding.

17 “(j) PRESCRIPTION ORDER REFERENCE.—For pur-  
18 poses of this section, reference to a prescription order for  
19 an identified individual patient includes, in the case of ani-  
20 mal drugs, a prescription order for a specific herd or flock  
21 (or other identified group) of animals.”.

22 (c) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)  
23 is amended—

24 (1) in subsection (e), by striking “417, 416,  
25 504” and inserting “417, 416, 503A(g), 504”; and

1 (2) by adding at the end the following:

2 “(ccc) The resale of a compounded drug that is la-  
3 beled ‘not for resale’ as required by section 503A.”.

4 (d) REPORT BY GAO.—Not later than November 1,  
5 2016, the Comptroller General of the United States shall  
6 conduct study and submit to Congress a report regarding  
7 the impact of this Act (and the amendments made by this  
8 Act) on the safety of animal drug compounding and the  
9 availability of safe and effective drugs for animals.

10 **SEC. 3. OTHER REQUIREMENTS RELATING TO**  
11 **COMPOUNDING MANUFACTURERS.**

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

14 “(bb) If it is a compounded drug and the labeling  
15 does not include the information as required by sub-  
16 sections (f)(1)(C) and (g)(4) of section 503A, as applica-  
17 ble.

18 “(cc) If it is a drug, and it was compounded by a  
19 compounding manufacturer for which fees have not been  
20 paid as required by section 503A(g).”.

21 (b) APPLICATION OF INSPECTION REQUIREMENTS TO  
22 COMPOUNDING MANUFACTURERS.—Section 704(a)(2)  
23 (21 U.S.C. 374(a)(2)) is amended by adding at the end  
24 the following flush text:

1 “The exemption in subparagraph (A) does not apply with  
2 respect to compounding manufacturers (as such term is  
3 defined in section 503A).”.

4 (c) ADULTERATION OF COMPOUNDED ANIMAL  
5 DRUGS CONTAINING DRUG RESIDUES.—Section  
6 402(a)(2)(C) is amended by striking “512;” and inserting  
7 “512; or (iii) any residue from a compounded animal  
8 drug;”.

9 **SEC. 4. IMPLEMENTATION.**

10 In promulgating any regulations to implement this  
11 Act (and the amendments made by this Act), the Sec-  
12 retary of Health and Human Services shall—

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

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

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

21 **SEC. 5. EFFECTIVE DATE.**

22 This Act (and the amendments made by this Act)  
23 shall take effect on the date that is 1 year after the date  
24 of enactment of this Act.

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