OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

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SETTLEMENT AGREEMENT WITH THE OHIO STATE BOARD OF PHARMACY

Docket Number 060626-089

in the matter of:

HOME MEDICAL ENHANCEMENT SERVICES, INC.
c/o Dino Martis, President
7798 Reading Road, Suite 5
Cincinnati, Ohio 45237

Terminal Distributor Number 02-1299000

This settlement agreement is entered into by and between Home Medical Enhancement Services, Inc. and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. Of the Ohio Revised Code.

Home Medical Enhancement Services, Inc. enters into this agreement being fully informed of its rights afforded under Chapter 119. Of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, the right to appeal. Home Medical Enhancement Services, Inc. acknowledges that by entering into this agreement it has waived its rights under Chapter 119. of the Revised Code.

WHEREAS, the State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may impose a monetary penalty on the license holder, for violation of any of the enumerated grounds of Section 4729.57 of the Ohio Revised Code.

WHEREAS, Home Medical Enhancement Services, Inc. is a licensed terminal distributor of dangerous drugs in the State of Ohio.

WHEREAS, on or about June 26, 2006, pursuant to Chapter 119. of the Ohio Revised Code, Home Medical Enhancement Services, Inc. was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was scheduled. The June 26, 2006, Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the Board of Pharmacy indicate that Home Medical Enhancement Services, Inc. is licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs. Records further reflect that Dino Martis is the president of the corporation.

(2) Home Medical Enhancement Services, Inc. did, on or about July 18, 2005, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded and dispensed Rx #22795, labeled as albuterol 2.5 mg/ipratropium 0.5 mg/triamcinolone 0.2 mg 2.5 mL #30 with 90 day expiration date; when potency was tested, the product tested only 55% of the labeled triamcinolone on August 18, 2005. Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(3) Home Medical Enhancement Services, Inc. did, on or about the following dates, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded on July 26, 2005, and dispensed the following prescriptions, labeled as albuterol 2.5 mg/ipratropium 0.5 mg/triamcinolone 0.4 mg 2.5 mL with 90 day expiration date from date of compounding; when potency was tested, the product tested only 27.5% of the labeled triamcinolone on August 18, 2005.

Rx #28738 for quantity 120 on 07/26/05
Rx #23522 for quantity 60 on 08/09/05

Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(4) Home Medical Enhancement Services, Inc. did, on or about the following dates, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded on July 29, 2005, and dispensed the following prescriptions, labeled as albuterol 2.5 mg/ipratropium 0.5 mg/betamethasone 80 mcg 2.5 mL with 90 day expiration date from date of compounding; when potency was tested, the product tested only 42.4% of the labeled albuterol amount and only 40% of the labeled ipratropium on August 15, 2005.

Rx #28792 for quantity 90 on 08/01/05
Rx #26259 for quantity 120 on 08/04/05

Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(5) Home Medical Enhancement Services, Inc. did, on or about September 6, 2005, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded and dispensed the following prescriptions, labeled as formoterol 12 mcg/budesonide 0.5 mg 2.5 mL with 90 day expiration date; when potency was tested, the product tested only 73.6% of the labeled formoterol on September 7, 2005.

Rx #29727 for quantity 30/60*
Rx #29728 for quantity 30/60*

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

Rx #25270 for quantity 30/60*
Rx #25165 for quantity 30/60*
Rx #25430 for quantity 30/60*

Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(6) Home Medical Enhancement Services, Inc. did, on or about September 12, 2005, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded and dispensed Rx #23522, labeled as albuterol 2.5 mg/ipratropium 0.5 mg/triamcinolone 0.4 mg 2.5 mL #30/60* with 90 day expiration date; when potency was tested, the product tested only 85% of the labeled triamcinolone on September 13, 2005. Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(7) Home Medical Enhancement Services, Inc. did, on or about the following dates, sell and/or hold or offer for sale a drug that was misbranded, to wit: the pharmacy compounded and dispensed the following prescriptions, labeled as formoterol 12 mcg/budesonide 0.5 mg 2.5 mL that was compounded and not terminally sterilized on 11/3/05; the testing laboratory notified Home Medical Enhancement Services, Inc. on November 14, 2005, that there was fungal contamination in the product. Though 23 patients were notified to discard the medication, some patients had inhaled some of the product.

Rx #26577 for quantity 60 on 11/09/05
Rx #30702 for quantity 60 on 11/09/05
Rx #31305 for quantity 60 on 11/09/05
Rx #31315 for quantity 60 on 11/09/05
Rx #31317 for quantity 30 on 11/09/05
Rx #31318 for quantity 60 on 11/09/05
Rx #31321 for quantity 60 on 11/09/05
Rx #31323 for quantity 60 on 11/09/05
Rx #29727 for quantity 60 on 11/09/05
6 on 11/11/05
Rx #31336 for quantity 60 on 11/09/05
Rx #31338 for quantity 60 on 11/09/05
Rx #30071 for quantity 60 on 11/09/05
Rx #25430 for quantity 60 on 11/09/05
Rx #28683 for quantity 60 on 11/09/05
Rx #25093 for quantity 60 on 11/09/05
Rx #26378 for quantity 60 on 11/09/05
Rx #26788 for quantity 60 on 11/09/05
Rx #30661 for quantity 60 on 11/10/05
Rx #31381 for quantity 60 on 11/10/05
Rx #31387 for quantity 60 on 11/10/05
Rx #31011 for quantity 60 on 11/10/05
Rx #31426 for quantity 60 on 11/10/05
Rx #31433 for quantity 60 on 11/10/05

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.

(8) Home Medical Enhancement Services, Inc. did, on or about the following dates, fail to maintain a quality assurance program wherein appropriate beyond use dates were assigned to compounded products, to wit: ninety (90) day beyond use dating was used on the following compounded products without justification and continued verification:

(a) Compounded formoterol 12 mcg/budesonide 0.5 mg 2.5 mL with 90 day beyond use dating on lot 05080901 was dispensed as:

Rx #26577 for quantity 60 on 08/11/05
Rx #29466 for quantity 60 on 08/11/05
Rx #29072 for quantity 60 on 08/15/05
Rx #25624 for quantity 60 on 08/16/05
Rx #24218 for quantity 60 on 08/16/05
Rx #29584 for quantity 30 on 08/16/05
Rx #27568 for quantity 60 on 08/17/05

Subsequent lab report on 10/13/05 (approx. 60 days) documented subpotency of budesonide at 86%.

(b) Compounded formoterol 12 mcg/budesonide 0.5 mg 2.5 mL with 90 day beyond use dating on lot 05091903 was dispensed as:

Rx #30328 for quantity 60 on 09/22/05
Rx #25974 for quantity 60 on 09/22/05
Rx #26913 for quantity 30 on 09/22/05
Rx #24194 for quantity 30/60* on 09/23/05
Rx #29541 for quantity 30/60* on 10/03/05
Rx #29888 for quantity 30 on 10/03/05
Rx #30559 for quantity 60 on 10/03/05
Rx #24218 for quantity 30/60* on 10/19/05

Subsequent lab report on 10/24/05 (approx. 30 days) documented subpotency of budesonide at 84%. None of the prescriptions were recalled.

Such conduct is in violation of Rule 4729-19-04(H) of the Ohio Administrative Code.

(9) Home Medical Enhancement Services, Inc. did, on or about the following dates, fail to maintain a quality assurance program to monitor product integrity specifically using end product testing of compounded products, to wit: the following compounded products were not tested for potency and/or sterility, fungal contamination, and endotoxins in violation of the Home Medical Enhancement Services, Inc. undated written policy concerning lab testing:

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

(a) Lot 05082201: albuterol 2.5 mg/ipratropium 0.5 mg/triamcinolone 0.2 mg 2.5 mL dispensed as:

Rx #22795 for quantity 30 on 08/22/05

No labs (potency, sterility, fungal, endotoxin) were requested. Previous compounding of this formula on 07/18/05 was subpotent. Formula did not have a terminal sterilization step.

(b) Lot 05093003: albuterol 2.5 mg/ipratropium 0.5 mg/triamcinolone 0.2 mg 2.5 mL dispensed as:

Rx #22795 for quantity 30 on 09/30/05

No sterility, fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(c) Lot 05101001: albuterol 2.5 mg/ipratropium 0.5 mg/dexamethasone 0.2 mg 2.5 mL dispensed as:

Rx #27543 for quantity 120 on 10/10/05
Rx #27136 for quantity 90 on 10/27/05
Rx #29576 for quantity 90 on 11/01/05

No labs (potency, sterility, fungal, endotoxin) were requested.

(d) Lot 05101104: albuterol 2.5 mg/ipratropium 0.5 mg/betamethasone 80 mcg 2.5 mL dispensed as

Rx #28792 for quantity 30/90* on 10/12/05
Rx #26259 for quantity 60/120* on 10/21/05
Rx #26259 for quantity 60/120* on 10/21/05

No labs (potency, sterility, fungal, endotoxin) were requested.

(e) Lot 05092001: albuterol 1.25 mg/ipratropium 0.5 mg 2.5 mL dispensed as:

Rx #29511 for quantity 30/120* on 09/20/05
Rx #27765 for quantity 30 on 10/12/05
Rx #27569 for quantity 90 on 10/18/05
Rx #29511 for quantity 120 on 10/25/05

No labs (potency, sterility, fungal, endotoxin) were requested.

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

(f) Lot 05093001: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #30642 for quantity 60 on 10/07/05
Rx #29657 for quantity 60 on 10/07/05
Rx #30636 for quantity 60 on 10/07/05
Rx #30071 for quantity 60 on 10/07/05
Rx #30657 for quantity 60 on 10/10/05
Rx #27531 for quantity 30/60* on 10/10/05

No sterility, fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(g) Lot 05093002: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #27704 for quantity 60 on 10/10/05
Rx #30661 for quantity 60 on 10/10/05
Rx #27531 for quantity 30/60* on 10/10/05
Rx #25430 for quantity 60 on 10/10/05
Rx #29613 for quantity 60 on 10/11/05
Rx #26577 for quantity 60 on 10/12/05

No sterility, fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(h) Lot 05101101: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #30692 for quantity 60 on 10/12/05
Rx #30702 for quantity 60 on 10/12/05
Rx #25065 for quantity 60 on 10/17/05
Rx #25624 for quantity 60 on 10/17/05
Rx #30173 for quantity 60 on 10/17/05
Rx #30158 for quantity 60 on 10/18/05
Rx #30795 for quantity 60 on 10/18/05

No fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(i) Lot 05101102: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #30161 for quantity 60 on 10/19/05
Rx #29079 for quantity 60 on 10/19/05
Rx #29637 for quantity 60 on 10/19/05
Rx #24219 for quantity 30/60* on 10/19/05
Rx #30810 for quantity 60 on 10/19/05
Rx #29072 for quantity 60 on 10/19/05
Rx #30116 for quantity 60 on 10/20/05

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

No fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(j) Lot 05101103: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #29728 for quantity 60 on 10/20/05
Rx #29639 for quantity 60 on 10/20/05
Rx #30779 for quantity 60 on 10/21/05
Rx #29698 for quantity 60 on 10/21/05
Rx #30864 for quantity 60 on 10/21/05
Rx #27568 for quantity 60 on 10/24/05
Rx #25270 for quantity 60 on 10/24/05

No fungal or endotoxin testing were requested. Formula did not have a terminal sterilization step.

(k) Lot 05102101: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #30893 for quantity 60 on 10/24/05
Rx #30882 for quantity 60 on 10/24/05
Rx #30884 for quantity 60 on 10/24/05
Rx #30880 for quantity 60 on 10/24/05
Rx #25974 for quantity 60 on 10/24/05
Rx #24194 for quantity 60 on 10/24/05

No fungal or endotoxin testing were requested; formula did not have a terminal sterilization step. No potency was requested; one of three previous testings for this formula was >5% variance from expected amount of budesonide.

(l) Lot 05102102: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #30367 for quantity 60 on 10/25/05
Rx #30315 for quantity 60 on 10/25/05
Rx #30328 for quantity 60 on 10/25/05
Rx #30915 for quantity 60* on 10/25/05
Rx #30924 for quantity 60 on 10/25/05
Rx #30922 for quantity 60 on 10/25/05
Rx #25165 for quantity 60 on 10/27/05

No fungal or endotoxin testing were requested; formula did not have a terminal sterilization step. No potency was requested; one of three previous testings for this formula was >5% variance from expected amount of budesonide.

* The original documents detailed said quantities as the amounts dispensed. It is undetermined from a reading of these records the actual amounts dispensed. On all such occasions, however, at least the minimum noted were dispensed.

(m) Lot 05102103: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #29829 for quantity 60 on 10/31/05
Rx #30526 for quantity 60 on 10/31/05
Rx #26047 for quantity 60 on 10/31/05
Rx #29466 for quantity 60 on 10/31/05
Rx #29583 for quantity 60 on 10/31/05

No fungal or endotoxin testing were requested; formula did not have a terminal sterilization step. No potency was requested; one of three previous testings for this formula was >5% variance from expected amount of budesonide.

(n) Lot 05102104: formoterol 12 mcg/budesonide 0.5 mg 2 mL dispensed as:

Rx #31059 for quantity 60 on 10/31/05
Rx #29670 for quantity 60 on 10/31/05
Rx #30497 for quantity 60 on 10/31/05
Rx #30495 for quantity 60 on 10/31/05
Rx #30448 for quantity 60 on 10/31/05
Rx #31095 for quantity 60 on 11/01/05
Rx #29541 for quantity 60 on 11/01/05

No fungal or endotoxin testing were requested; formula did not have a terminal sterilization step. No potency was requested; one of three previous testings for this formula was >5% variance from expected amount of budesonide.

Such conduct is in violation of Rule 4729-19-04(H) of the Ohio Administrative Code.

(10) Home Medical Enhancement Services, Inc. did, from June 8, 2005, through November 14, 2005, fail to prepare and maintain a policy and procedure manual regarding the compounding, dispensing, and delivery of sterile product prescriptions. After admonition by a Board agent, a manual (containing only two undated and unsigned policies regarding lab testing and product recalls) was created but the facility was noncompliant with said manual. Such conduct is in violation of Rule 4729-19-04(B) of the Ohio Administrative Code.

(11) Home Medical Enhancement Services, Inc., from November 18, 2005, through December 20, 2005, as a terminal distributor of dangerous drugs did fail to have a Responsible Person employed by the facility. Such conduct is in violation of Rule 4729-5-11(B)(1) of the Ohio Administrative Code.

Home Medical Enhancement Services, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated June 26, 2006; however, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Home Medical Enhancement Services, Inc. knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

(1) Home Medical Enhancement Services, Inc. agrees to the imposition of a monetary penalty of fifteen hundred dollars ($1500.00), due and owing within thirty (30) days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126.

(2) Home Medical Enhancement Services, Inc. agrees that it has already, and will continue to, require its pharmacist engaging in compounding to maintain competency in compounding and attend appropriate approved training to meet industry and legal standards in compounding services.

Home Medical Enhancement Services, Inc. acknowledges that it has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Home Medical Enhancement Services, Inc. waives any and all claims or causes of action it may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Home Medical Enhancement Services, Inc. waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.
This agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

/s/ Dino Martis, President
Home Medical Enhancement Services, Inc. Date Signed: 05/02/07

/s/ James Lindon, Attorney for Respondent Date Signed: 05/09/07

/s/ James E. Turner, President,
Ohio State Board of Pharmacy Date Signed: 05/08/07

/s/ Sally Ann Steuk,
Ohio Assistant Attorney General Date Signed: 05/08/07
