DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2016–N–2462]

Amendments to the Regulation
Regarding the List of Drug Products
That Have Been Withdrawn or
Removed From the Market for Reasons
of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHSP.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is
proposing to amend its regulations to
revise the list of drug products that have
been withdrawn or removed from the
market because the drug products or
components of such drug products have
been found to be unsafe or not
effective. Drugs appearing on this list may not be
compounded under the exemptions
provided by sections 503A and 503B of
the Federal Food, Drug, and Cosmetic
Act (the FD&C Act). Specifically, the
proposed rule would add three entries
to this list of drug products.

DATES: Submit either electronic or
written comments on the proposed rule

ADDRESSES: You may submit comments
as follows:

Electronic Submissions

Submit electronic comments in the
following way:

• Federal eRulemaking Portal: http://
www.regulations.gov. Follow the
instructions for submitting comments.
Comments submitted electronically,
including attachments, to http://
www.regulations.gov will be posted
to the docket unchanged. Because your
comment will be made public, you are
solely responsible for ensuring that your
comment does not include any
confidential information that you or a
third party may not wish to be posted,
such as medical information, your or
anyone else’s Social Security number, or
confidential business information, such
as a manufacturing process. Please note
that if you include your name, contact
information, or other information that
identifies you in the body of your
comments, that information will be

• If you want to submit a comment
with confidential information that you
do not wish to be made available to the
public, submit the comment as a
written/paper submission and in the
manner detailed (see “Written/Paper
Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as
follows:

• Mail/Hand delivery/Courier (for
written/paper submissions): Division of
Dockets Management (HFA–305), Food
and Drug Administration, 5630 Fishers
Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments
submitted to the Division of Dockets
Management, FDA will post your
comment, as well as any attachments,
except for information submitted,
made publicly available, submit your
comments only as a written/paper
submission. You should submit two
copies total. One copy will include the
information you claim to be confidential
with a heading or cover note that states
“This Document Contains
Confidential Information.” The
Agency will review this copy, including
the claimed confidential information, in
its consideration of comments. The
second copy, which will have the
claimed confidential information
redacted/blacked out, will be available
for public viewing and posted on
http://www.regulations.gov. Submit both
copies to the Division of Dockets
Management. If you do not wish your
name and contact information to be
made publicly available, you can
provide this information on the cover
sheet and not in the body of your
comments and you must identify this
information as “confidential.” Any
information marked as “confidential”
will not be disclosed except in
accordance with 21 CFR 10.20 and other
applicable disclosure law. For more
information about FDA’s posting of
comments to public dockets, see 80 FR
56469, September 18, 2015, or access
the information at: http://www.fda.gov/

6 Citizens United v. FEC, 558 U.S. 310, 368 (2010)
(quoting First Nat’l Bank of Boston v. Bellotti, 435
U.S. 765, 792 n.32 (1978)).
One of the conditions that must be satisfied to qualify for the exemptions set forth in sections 503A and 503B of the FD&C Act is that the compounder does not compound a drug product that has been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.

B. Summary of the Major Provisions of the Proposed Regulatory Action

We are proposing that the following drugs that have been withdrawn or removed from the market because such drug products have been found to be unsafe or not effective be added to the list in § 216.24. The specific entries proposed for addition to the list for each of these drugs are provided as follows:

- **Aprotinin**: All drug products containing aprotinin.
- **Bromocriptine mesylate**: All drug products containing bromocriptine mesylate for prevention of physiological lactation.
- **Ondansetron hydrochloride**: All intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride.

C. Costs and Benefits

The Agency is not aware of any routine use of the drug products that FDA is proposing to add to the withdrawn or removed list and, therefore, does not estimate any compliance costs or loss of sales as a result of the prohibition against compounding these drug products for human use. The Agency has determined that this rulemaking is not a significant regulatory action as defined by Executive Order 12866.

II. Background

A. Relevant Provisions of the Statute

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs).

In addition, section 503B of the FD&C Act describes the conditions that must be satisfied for a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility to be exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360ee–1) (concerning drug supply chain security).

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the compounder does not compound a drug product that appears on a list published by the Secretary of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (withdrawn or removed list) (see sections 503A(b)(1)(C), 503B(a)(4), and 503B(a)(11) of the FD&C Act).

B. The List of Drug Products in § 216.24

The drug products listed in § 216.24 (the withdrawn or removed list) have been withdrawn or removed from the market because they have been found to be unsafe or not effective and are ineligible for the exemptions set forth in sections 503A and 503B of the FD&C Act. A drug product that is included in the list codified at § 216.24 is not eligible for the exemptions provided in section 503A(a) of the FD&C Act, and is subject to sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act in addition to other applicable provisions, if compounded. In addition, a drug that is included in the list codified at § 216.24 cannot qualify for the exemptions provided in section 503B(a) of the FD&C Act, and is subject to sections 502(f)(1), 505, and 582 of the FD&C Act, in addition to other applicable provisions, if compounded.

C. Regulatory History of the List

Following the addition of section 503A to the FD&C Act on November 21, 1997, through the enactment of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), FDA proposed a rule in the Federal Register of October 8, 1998 (63 FR 54082), to establish the original list of drug products that have been withdrawn or removed from the market because the drug products or the components of such drug products have been found to be unsafe or not effective (1998 proposed rule) and therefore were not permitted to be compounded for human use under the exemptions provided by section 503A(a).

In the Federal Register of March 8, 1999 (64 FR 10944), FDA published a final rule that codified the original list in § 216.24 (1999 final rule).

Following the addition of section 503B to the FD&C Act on November 27, 2013, through the enactment of the Drug Quality and Security Act (Pub. L. 113–54), FDA proposed to amend the list in § 216.24 on July 2, 2014 (79 FR 37687); FDA published the final rule to amend § 216.24 in the Federal Register of October 7, 2016 (81 FR 69668) (2016 final rule). Given that nearly identical
undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at increased risk for blood loss and blood transfusion.”

Prominent known adverse reactions associated with the use of the drug included anaphylactic reactions (with some deaths reported) and impaired renal function. In January 2006, Mangano et al. published a report that described the results from a retrospective analysis of the use of aprotinin compared to two other antifibrinolytic drugs (tranexamic acid and aminocaproic acid) or no antifibrinolytic drugs in 4,374 patients undergoing cardiac surgery (Ref. 1). The conclusions were that there was a statistically greater likelihood of the development of renal dysfunction and the need for hemodialysis, stroke, encephalopathy, myocardial infarction, and congestive heart failure in patients treated with aprotinin than with the other antifibrinolytic drugs or no antifibrinolytic drugs. On February 8, 2006, FDA issued a Public Health Advisory on TRASYLOL, NDA 20304, that called attention to this new information (Ref. 2). On September 21, 2006, FDA convened a meeting of its Cardiovascular and Renal Advisory Committee to evaluate these and other data for the drug (see http://www.fda.gov/ohrms/dockets/ac/cder07.htm#CardiovascularRenal for meeting documents from the September 21, 2006, Cardiovascular and Renal Advisory Committee meeting). The Cardiovascular and Renal Advisory Committee voted that the benefits of TRASYLOL, NDA 20304, compared to its risks warranted continued approval for the indication (Yes, 18; No, 0; Abstain, 1). Before the advisory committee meeting, the sponsor had funded a study that evaluated a medical database for the outcomes of patients undergoing coronary artery bypass graft surgery (CABG) treated with aprotinin or other antifibrinolitics, which concluded that there was an increased risk of in-hospital death in the aprotinin-treated patients compared to those in patients treated with aminocaproic acid. This information was subsequently published in 2008 by Schneeweiss et al. (Ref. 3). In 2007, Mangano et al. published a report in 3,876 patients undergoing CABG surgery describing a higher mortality after 5 years for those treated with aprotinin compared to those treated with no antifibrinolytic drugs (Ref. 4). In the 2007 Mangano study, patients treated with tranexamic acid or aminocaproic acid did not experience a higher mortality at 5 years compared to patients treated with no antifibrinolytic drug. These data led to a reconvening of the Cardiovascular and Renal Advisory Committee in a joint meeting with the Drug Safety and Risk Management Advisory Committee on September 12, 2007 (joint meeting, at which these and other data were reviewed (see http://www.fda.gov/ohrms/dockets/ac/cder07.htm#CardiovascularRenal for meeting documents from the September 12, 2007, Cardiovascular and Renal Advisory Committee meeting). The Committees at the joint meeting were informed that there was an ongoing prospective randomized trial of aprotinin, tranexamic acid, and aminocaproic acid in patients undergoing CABG surgery with cardiopulmonary bypass in Canada (named the BART study), but that the results would not be available for several years. Some of the Committee members at the joint meeting stated that the issue should be revisited once the data from the BART study were available. The Advisory Committees at the joint meeting voted that TRASYLOL, NDA 20304, should continue to be authorized to be marketed in the United States. Shortly after the joint meeting, FDA was informed that the Data Monitoring and Safety Committee for the BART study had recommended that the BART trial be terminated early because there appeared to be a greater frequency of death in patients treated with aprotinin (6.0 percent) compared to those treated in the combined tranexamic acid plus aminocaproic acid group (3.9 percent). The study was subsequently published in 2008 by Fergusson (Ref. 5). On October 25, 2007, FDA issued a Safety Alert for Human Medical Products alerting the medical community about the preliminary data from the BART trial (Ref. 6). On November 5, 2007, FDA issued a press release stating that, at the Agency’s request, the sponsor had made a decision to suspend the marketing of TRASYLOL, NDA 20304, pending a review of the BART data for safety (Ref. 7). Although some of the data from the BART trial were submitted to FDA and the sponsor submitted its analysis of the data that was made available to the company, FDA was never successful in obtaining the raw data from the trial. Therefore, FDA was not able to conduct its own analyses of the trial data. TRASYLOL, NDA 20304, has not returned to the U.S. market since the sponsor announced its decision to suspend marketing in 2007. Aprotinin was made available to the sponsor for the treatment of certain surgical patients with an established medical need using...
a treatment protocol under an investigational new drug application (IND) (Ref. 8). Expanded access to aprotinin through this treatment protocol is no longer available (see https://clinicaltrials.gov/ct2/show/NCT00611845?term=aprotinin&rank=4).

FDA is not aware of any data that would give us reason to believe that the safety issues identified as having been associated with aprotinin should be restricted to a particular formulation, concentration, indication, route of administration, or dosage form. For these reasons, FDA is proposing to include all drug products containing aprotinin on the withdrawn or removed list.


Bromocriptine mesylate was associated with risks of hypertension, seizures, and cardiovascular accidents, and the unfavorable benefit-risk balance was specified use of bromocriptine mesylate for the prevention of physiological lactation. In 1980, PARLODEL (bromocriptine mesylate) was approved for the prevention of physiological lactation as an acceptable alternative to estrogenic therapy. Subsequently, FDA received postmarket reports of serious and life-threatening adverse reactions (hypertension, seizures, and cerebrovascular accidents) associated with the use of bromocriptine mesylate to suppress lactation. According to the approved labeling for PARLODEL, dated July 15, 1988 (Ref. 9), serious adverse reactions reported in postpartum women included 50 cases of hypertension, 38 cases of seizures (including 4 cases of status epilepticus), 15 cases of strokes, and 3 cases of myocardial infarction. These cases were discussed at a 1989 Fertility and Maternal Health Drugs Advisory Committee meeting (Ref. 10). FDA presented reports of its safety findings, which included 28 reports of hypertension, 36 reports of seizures, and 19 reports of cerebrovascular accidents. FDA had received 85 cases of serious adverse events, including 10 deaths, since the approval of bromocriptine mesylate for lactation suppression in 1980 (August 23, 1994) (59 FR 43347). The Fertility and Maternal Health Drugs Advisory Committee recommended that no drug then labeled for lactation suppression including bromocriptine mesylate be used for this indication.

FDA subsequently asked that all manufacturers of these drugs voluntarily remove this indication from drug labeling. All but Sandoz, the manufacturer of PARLODEL, complied with FDA’s request. In a document published in the Federal Register of August 23, 1994, FDA concluded that the risks of hypertension, seizures, and cardiovascular accidents outweighed the product’s marginal benefit in preventing postpartum lactation. Accordingly, FDA proposed to withdraw approval of the indication recommending bromocriptine mesylate for preventing physiological lactation in the NDA for PARLODEL, under section 505(e) of the FD&C Act, on the basis that the product is no longer shown to be safe for this indication. FDA withdrew approval of PARLODEL for the indication of prevention of physiological lactation in a document published in the Federal Register of January 17, 1995 (60 FR 3404). Withdrawal of PARLODEL’s indication for the prevention of physiological lactation became effective on February 16, 1995. FDA’s review of the withdrawal indicates that the withdrawal of bromocriptine mesylate for prevention of physiological lactation was fundamentally based on an unfavorable benefit-risk balance specific to this indication and not to other approved indications (such as treatment of Parkinson’s disease, acromegaly, and prolactin-secreting adenomas). For this reason, FDA is proposing to include all drug products containing bromocriptine mesylate for prevention of physiological lactation on the withdrawn or removed list.

c. Ondansetron hydrochloride: All intravenous drug products containing greater than a 16 mg single IV dose of ondansetron hydrochloride.

Ondansetron (ondansetron HCl) Injection, USP, 32 mg in 50 milliliters (mL), single intravenous (IV) dose, was associated with a specific type of irregular heart rhythm called QT interval prolongation, and the data suggest that any dose above the maximum recommended of 16 mg per dose intravenously has the potential for increased risk of QT prolongation. In September 2011, FDA issued a Drug Safety Communication alerting health care professionals that the 32 mg single IV dose of ZOFRAN (ondansetron HCl) and generic versions of that product could increase the risk of abnormal changes in the electrical activity of the heart, which could result in a potentially fatal abnormal heart rhythm (Ref. 11). Based on data subsequently collected from a study conducted at FDA’s request by ZOFRAN’s sponsor, GlaxoSmithKline (GSK), that identified a significant QT prolongation effect in connection with the 32 mg single IV dose, FDA approved GSK’s supplemental application to remove the 32 mg single IV dose information from the labeling for ZOFRAN and has worked with manufacturers of all 32 mg single IV dose ondansetron HCl products to have them removed from the market. On June 29, 2012, FDA issued a Drug Safety Communication to notify health care professionals that the 32 mg single IV dose of ondansetron HCl, indicated for prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in adult patients, should be avoided due to the risk of QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm (Ref. 12). Subsequently, FDA informed the holders of one NDA and four ANDAs for ondansetron HCl that the agency believes that, in light of the safety concern associated with ondansetron HCl in the 32 mg single IV dose, these drug products should be removed from the market. The application holders agreed to voluntarily remove their respective 32 mg single IV dose ondansetron HCl products from the market and requested that FDA withdraw approval of their respective applications under 21 CFR 314.150(d). On December 4, 2012, FDA issued an updated Drug Safety Communication alerting health care professionals that these products would be removed from the market because of their potential for serious cardiac risks (Ref. 13). In the Federal Register of June 10, 2015 (80 FR 32966), FDA announced that it was withdrawing the approval of these five applications. On the same day, in a different document in the Federal Register (80 FR 32962), FDA announced its determination under 21 CFR 314.161 and 314.162(a)(2) that the NDA for Ondansetron (ondansetron HCl) Injection, USP, 32 mg/50 mL, single IV dose was withdrawn from sale for reasons of safety. As explained in the review of ondansetron HCl 32 mg single IV dose for the withdrawn or removed list (see tab 5 of the FDA briefing document for the June 17–18, 2015, Pharmacy Compounding Advisory Committee, available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm431285.htm), for those approved products for IV ondansetron HCl that remain on the market, the current dosage and administration recommendation for adults and pediatric patients (6 months to 18 years) is three 0.15 mg/kilogram doses, up to a maximum of 16 mg intravenously over 15 minutes, and any dose above the maximum recommended
16 mg per IV dose has the potential for increased risk of QT prolongation. For these reasons, FDA is proposing to include all IV drug products containing greater than a 16 mg single dose of ondansetron HCl on the withdrawn or removed list.

On June 17, 2015, FDA presented these three proposed entries to the Pharmacy Compounding Advisory Committee (see the Federal Register of May 22, 2015 (80 FR 29771)). In addition to these three proposed entries, FDA presented a potential entry for all drug products containing more than 325 mg of acetaminophen per dosage unit to the Pharmacy Compounding Advisory Committee. The addition of all drug products containing more than 325 mg of acetaminophen per dosage unit to the list remains under consideration by the Agency.

The Pharmacy Compounding Advisory Committee voted in favor of including each of FDA’s four proposed entries on the list. Although an open public hearing session was scheduled at this meeting to allow members of the public to present their views and opinions on the proposed entries to the committee members and the Agency prior to the vote by the Pharmacy Compounding Advisory Committee, no members of the public signed up to participate. A transcript of the June 2015 Pharmacy Compounding Advisory Committee meeting and briefing information that includes reviews and background on the proposed entries may be found at the Division of Dockets Management (see ADDRESSES) and at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm431285.htm.

IV. Legal Authority

Sections 503A and 503B of the FD&C Act provide the principal legal authority for this proposed rule. As described previously in the Background section of this document, section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act (sections 501(a)(2)(B), 502(f)(1), and 505). One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section 503A(b)(1)(C) of the FD&C Act). Section 503A(c)(1) of the FD&C Act also states that the Secretary shall issue regulations to implement section 503A, and that before issuing regulations to implement section 503A(b)(1)(C) pertaining to the withdrawn or removed rule, among other sections, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. Section 503B of the FD&C Act describes the conditions that must be satisfied for a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility to be exempt from three sections of the FD&C Act (sections 502(f)(1), 505, and 582). One of the conditions in section 503B of the FD&C Act that must be satisfied to qualify for the exemptions is that the drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective (see section 503B(a)(4)). To be eligible for the exemptions in section 503B, a drug must be compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with section 503B, including as provided in section 503B(a)(4).

Thus, sections 503A and 503B of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this proposed rule revising FDA’s regulations on drug products withdrawn or removed from the market because the drug product or a component of the drug product have been found to be unsafe or not effective in §21.24.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small businesses are not expected to incur any compliance costs or loss of sales due to this regulation, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

This proposed rule would amend §216.24 concerning human drug compounding. Specifically, the proposed rule would add to or modify the list of drug products that may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section II of this document). We are proposing to add three entries to the list. We are not aware of any routine compounding for human use of the drug products that are the subject of this proposed rule, and therefore do not estimate any compliance costs or loss of sales if the proposal is adopted. However, we invite the submission of comments and solicit current compounding use data for these drug products, if they are compounded for human use.
Unless we certify that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options to minimize any significant economic impact of a regulation on small entities. Most pharmacies meet the Small Business Administration definition of a small entity, which is defined as having annual sales less than $25.5 million for this industry. We are not aware of any routine compounding of these drug products and do not estimate any compliance costs or loss of sales to small businesses as a result of the prohibition against compounding these drug products. Therefore, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, or on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 216 be amended as follows:

PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for part 216 continues to read as follows:


■ 2. Amend §216.24 by adding, in alphabetical order, to the list of drugs “Aprotinin”, “Bromocriptine mesylate”, and “Ondansetron hydrochloride” to read as follows:

§216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

* * * * *
Aprotinin: All drug products containing aprotinin.

* * * * *
Bromocriptine mesylate: All drug products containing bromocriptine mesylate for prevention of physiological lactation.

* * * * *
Ondansetron hydrochloride: All intravenous drug products containing greater than a 16 milligram single dose of ondansetron hydrochloride.

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Dated: October 11, 2016.
Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–25005 Filed 10–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2016–0029]

RIN 0651–AD10

Rule Recognizing Privileged Communications Between Clients and Patent Practitioners at the Patent Trial and Appeal Board


ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the rules of practice before the Patent Trial and Appeal Board to recognize that, in connection with discovery conducted in certain proceedings at the United States Patent and Trademark Office (USPTO or Office), communications between U.S.