other than English at home.[2] Marketers are well-aware of this trend, and today they often tout a wide array of products and services, including home loans, in languages other than English.

It is essential that our consumer protection laws keep pace with such marketplace realities, and we are pleased that the MAP Rule broadly bans deception in commercial communications concerning residential mortgages regardless of the language or languages in which they are made. For example, under the MAP Rule it can be unlawful to offer a consumer one set of terms in her native language but then deliver different terms in loan documents written in English.[3] In addition, because the ''net impression'' of an advertisement is the lynchpin of deception analysis,[4] a fine print disclaimer or qualifying statement may be insufficient to cure an otherwise misleading advertisement.[5] This principle, as applied to advertising that uses multiple languages, means that, in advertising that targets consumers in a language other than English, a disclaimer in English may be insufficient to cure misleading claims in another language.[6]

But there are many questions about the communication of mortgage loan terms that go beyond the scope of this rulemaking, among them whether mortgage disclosure documents should be provided to non-English speakers in languages other than English.[7] Congress has charged the Consumer Financial Protection Bureau with the long-overdue task of simplifying and clarifying mortgage disclosure documents,[8] and has granted the new agency broad rulemaking authority with respect to the advertising and communication of mortgage loan terms. We look forward to the results of the CFPB's work in this area, including its consideration of the needs of non-native English speaking consumers when carrying out that important mandate.[9]

More generally, given our country's changing demographics, we believe that government and industry alike will need to pay greater attention to ensuring that consumers, no matter what language they speak, have access to important information regarding their purchases and are protected from unfair and deceptive practices.

Appendix B—Response of Commissioner J. Thomas Rosch to the Concurring Statement of Commissioner Ramirez, in Which Chairman Leibowitz and Commissioner Brill Join

Final Rule: Mortgage Acts and Practices—Advertising

July 19, 2011

I agree with the concurring statement of Commissioner Ramirez concerning the Mortgages Acts and Practices—Advertising Rule to the extent it reiterates the assertions of the Statement of Basis and Purpose that the ''net impression'' of an advertisement is a touchstone of FTC deception analysis regardless of the language or combination of languages. It is also axiomatic that government and industry need to be vigilant that all consumers, regardless of what language they speak, are not victims of unfair and deceptive practices.

However, insofar as the concurring statement suggests that the Consumer Financial Protection Bureau should require that mortgage disclosure documents be provided to non-English speaking consumers in their native language, I disagree. There is no basis for making any recommendation to ''go beyond'' the MAP Rule or Section 5 as respects requirements that lenders furnish ''non-English speakers'' with disclosures that are not in English. *See* Concurring Statement at 3. Specifically, Census Bureau data showing that nearly 20 percent of people in the United States in 2007 ''reported speaking a language other than English at home'' (*id.* at 1) does not suggest that they could not read or understand English. Indeed, so far as the rulemaking record for the MAP Rule is concerned, it is my understanding that a majority of the comments received favored making disclosures only in English. Thus, there is currently no basis for the Federal government to burden this industry with disclosure requirements that would oblige the industry to make disclosures in a language other than English except when the ''net impression'' left by not doing so would violate Section 5.

[FR Doc. 2011–18605 Filed 7–20–11; 11:15 am]

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[2] U.S. Census Bureau, *Language Use in the United States: 2007* (Apr. 2010), *available at http://www.census.gov/prod/2010pubs/acs-12.pdf.*

[3] In fact, the FTC has challenged such a practice as deceptive under Section 5 of the FTC Act. *See FTC* v. *Mortgages Para Hispanos.com Corp.,* No. 4:06–cv19 (E.D. Tex. 2006) (alleging mortgage broker engaged in deceptive practices by orally offering Spanish-speaking customers one thing in Spanish and then delivering something else in loan documents written entirely in English).

[4] *See, e.g., FTC* v. *Cyberspace.com, LLC,* 453 F.3d 1196, 1200 (9th Cir. 2006); *FTC* v. *Nat'l Urological Group, Inc.,* 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008), *aff'd,* 356 Fed. App'x (11th Cir. 2009).

[5] *See, e.g., Cyberspace.com,* 453 F.3d at 1200.

[6] In 2008, the Board of Governors of the Federal Reserve System amended Regulation Z under the Truth in Lending Act to prohibit advertising certain information only in a foreign language while providing, in the same advertisement, other critical information in English. *See* Final Rule, Truth in Lending, 73 FR 44522, 44601 (Jul. 30, 2008) (codified at 12 CFR 226.24(i)(7)). This approach is consistent with longstanding FTC requirements that mandatory disclosures be made in the language of the target audience. *See* 16 CFR 14.9 (under FTC rules, cease-and-desist orders, and guides that require the ''clear and conspicuous'' disclosure of information, such disclosure must be made in the language of the target audience); 16 CFR 610.4(a)(3)(ii) (in marketing free credit reports, mandatory disclosures must be made in the same language as that principally used in the advertisement); 16 CFR 429.1(a) (in door-to-door sales, failure to furnish a completed receipt or contract in the same language as the oral sales presentation is an unfair and deceptive act or practice); 16 CFR 455.5 (where used car sales pitches are conducted in Spanish, mandatory disclosures must be made in Spanish); 16 CFR 308.3(a)(1) (mandatory disclosures about pay-per-call services must be made in the same language as that principally used in the advertisement); *see also* FTC Final Rule, Free Annual File Disclosures, 75 FR 9726, 9733 (Mar. 3, 2010) (noting ''the Commission's belief that a disclosure in a language different from that which is principally used in an advertisement would be deceptive'').

[7] The CFPB has begun testing draft prototype mortgage disclosure documents in English and Spanish in advance of a formal rulemaking process. *See* CFPB, *Consumer Financial Protection Bureau Announces Initiative to Combine Mortgage Loan Disclosures* (May 18, 2011), *available at http://www.consumerfinance.gov/pressrelease/consumer-financial-protection-bureau-announces-initiative-to-combine-mortgage-loan-disclosures/.*

[8] *See generally James M. Lacko & Janis K. Pappalardo, Federal Trade Commission Staff Report, Improving Consumer Mortgage Disclosures: An Empirical Assessment of Current And Prototype Mortgage Disclosure Forms* (2007), *available at http://www.ftc.gov/os/2007/06/P025505Mortgage DisclosureReport.pdf.*

[9] Our colleague, Commissioner Rosch, expresses concern that we may be advancing an argument about mortgage disclosures that is not supported by the record before us. But far from prejudging the outcome of any work to be performed by the CFPB, we are simply highlighting some of the important consumer protection issues that may arise in connection with mortgage advertisements targeting consumers whose primary language is not English. As we noted above, the matters before the Commission in this rulemaking were narrow, and the evidence received on the issue of the use of multiple languages in advertising—a mere four comments—does not address the questions to be examined by the CFPB concerning improvements to mortgage disclosure documents. While this limited record does not purport to address such issues, we have no doubt that in considering this and other questions, the CFPB will develop a full and complete record that properly takes into account the impact on all stakeholders of any measure that is designed to ensure that consumers receive clear and accurate information to assist them in making sound decisions about mortgages.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

[CPSC Docket No. CPSC–2011–0007]

Poison Prevention Packaging Requirements; Exemption of Powder Formulations of Colesevelam Hydrochloride and Sevelamer Carbonate

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (''CPSC,'' ''Commission,'' or ''we'') is amending its child-resistant packaging requirements to exempt powder formulations of two oral prescription drugs, colesevelam hydrochloride and sevelamer carbonate. Colesevelam hydrochloride, currently marketed as Welchol®, is available in a powder formulation and is indicated to reduce elevated LDL cholesterol levels and improve glycemic control in adults with type 2 diabetes mellitus. Sevelamer carbonate, currently marketed as Renvela®, is also available as a powder formulation and is indicated for the control of elevated serum phosphorus in chronic kidney disease patients on dialysis. The rule exempts these

prescription drug products on the basis that child-resistant packaging is not needed to protect young children from serious injury or illness from powder formulations of colesevelam hydrochloride and sevelamer carbonate because the products are not acutely toxic, lack adverse human experience associated with acute ingestion, and, in powder form, are not likely to be ingested in large quantities by children under 5 years of age.

DATES: The rule becomes effective on July 22, 2011.

FOR FURTHER INFORMATION CONTACT: John Boja, Office of Compliance, Consumer Product Safety Commission, Bethesda, MD 20814–4408; telephone (301) 504–7300; *jboja@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. The Poison Prevention Packaging Act of 1970 and Implementing Regulations

The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, gives the Commission authority to establish standards for the ''special packaging'' of household substances, such as drugs, when child-resistant (''CR'') packaging is necessary to protect children from serious personal injury or illness due to the substance and the special packaging is technically feasible, practicable, and appropriate for such substance. Accordingly, CPSC regulations require that oral prescription drugs be in CR packaging. 16 CFR 1700.14(a)(10). The powder forms of cholestyramine and colestipol, two drugs that are chemically similar to colesevelam hydrochloride and sevelamer carbonate, currently are exempt from CR packaging. *Id.* 1700.14(a)(10)(v) and (xv).

CPSC regulations allow companies to petition the Commission for exemption from CR requirements. 16 CFR part 1702. Among the possible grounds for granting an exemption are that:

> The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using or ingesting the substance.

16 CFR 1702.17.

2. The Products for Which Exemptions Are Sought

a. Welchol® (Colesevelam Hydrochloride)

On February 24, 2009, Daiichi Sankyo, Inc. (''Daiichi'') petitioned the Commission to exempt the powdered form of colesevelam hydrochloride, which it markets as Welchol®, from the special packaging requirements for oral prescription drugs. The petitioner stated that the exemption is justified because of lack of toxicity and lack of adverse human experience with the drug. Welchol® has been marketed in tablet form and dispensed in CR packaging. On October 2, 2009, the U.S. Food and Drug Administration (''FDA'') approved a new powder formulation of the drug. The petition requested an exemption only for the powder dosage form of Welchol®. The product, in tablet form, would continue to be in CR packaging.

Welchol® is a bile acid sequestrant indicated as an adjunct to: (1) Reduce elevated low-density lipoprotein cholesterol (LDL–C) levels; and (2) improve glycemic control in adults with type 2 diabetes mellitus. The new dosage form of Welchol® provides 1.875 g or 3.75 g of the powdered drug in unit dose packages to be mixed with water and taken orally as a suspension. (A unit dose package of Welchol® is a pouch that contains an individual dose.)

b. Renvela® (Sevelamer Carbonate)

On March 6, 2009, Genzyme Corporation (''Genzyme'') petitioned the Commission to exempt the powdered form of sevelamer carbonate, which it markets as Renvela,® from the special packaging requirements for oral prescription drugs. The petitioner stated that the exemption is justified because of lack of toxicity and lack of adverse human experience with the drug.

Renvela® is a phosphate binder indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis. The tablets are marketed with a pill crusher for patients who have trouble swallowing the tablets. The company reformulated Renvela® as a powder to be taken as an oral suspension, and the FDA approved this powder formulation on August 12, 2009. The new dosage form of Renvela® provides either 0.8 g or 2.4 g of Renvela® powder in unit dose packages to be mixed with 2 ounces of water.

B. Proposed Rule

On February 16, 2011, we published a notice of proposed rulemaking (''NPR'') proposing to exempt from special packaging the powder forms of colesevelam hydrochloride (Welchol®) and sevelamer carbonate (Renvela®). 76 FR 8942. As explained in the preamble to the proposed rule, we considered the two exemption petitions together because Welchol® and Renvela® have similar chemical structures, biological properties, and powder formulations.

C. Toxicity and Human Experience Data

1. Summary of Data From Proposed Rule

As noted in the preamble to the proposed rule (76 FR at 8943), the systemic toxicity of colesevelam hydrochloride and sevelamer carbonate is limited because they are not absorbed from the gastrointestinal (GI) tract. There is no data indicating that either drug is acutely toxic. Acute toxicity is the type of toxicity that is of concern when considering whether CR packaging is appropriate. Even in patients taking these drugs chronically, the adverse effects are mostly minor, such as diarrhea, nausea, constipation, flatulence, and dyspepsia.

If a child were to ingest accidentally Welchol® or Renvela®, the potential for the occurrence of mild to moderate GI discomfort, such as indigestion, constipation, nausea, and vomiting does exist. However, a review of relevant data indicates that an acute ingestion of these drugs would not result in serious toxicity.

CPSC's CR packaging regulations exempt cholestyramine and colestipol in powder form, two bile acid sequestrants that are similar chemically to Welchol® and Renvela.® We have not found any relevant articles in the medical literature describing toxic effects following the acute ingestion of either cholestyramine or colestipol from 1975 through 2010.

As discussed in the preamble to the proposed rule (76 FR at 8944), we searched the following databases for incidents related to Welchol® and Renvela® occurring between 2000 and 2009: the Injury and Potential Injury Incident database (''IPII''), the National Electronic Injury Surveillance System database (''NEISS''), and the Death Certificates database (''DTHS''). We found one incident involving Welchol® in the NEISS database. In that incident, 11-month-old twin boys were taken to the emergency room after they had been playing with their grandmother's prescription medications. It is not clear how many, if any, pills the boys ingested, but the children were treated and released from the hospital. We also searched Poisindex,® Pub Med, and Google for Welchol,® Renvela,® colestipol, and cholestyramine, and found no relevant incidents of acute poisoning in humans.

Before publication of the proposed rule, and as noted therein, we also analyzed Medwatch reports obtained from the FDA. Medwatch is the FDA's program for reporting a serious adverse event, product quality problem, product

use error, or therapeutic inequivalence/failure that may be associated with the use of an FDA-regulated drug, biologic, medical device, dietary supplement, or cosmetic. (See *http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm*.) There may be adverse events that have occurred and are not reported in the Medwatch database. Also, the existence of a report in the database does not mean necessarily that the product actually caused the adverse event.

The FDA gave us 151 distinct incidents of adverse events associated with Welchol® reported through the Medwatch system. We excluded incidents where other medications may have caused the adverse event reported, resulting in 22 adverse events. Most adverse events reported to Medwatch were gastrointestinal or involved muscle pain, which is to be expected considering the adverse effects reported from clinical trials of Welchol.®

We also received reports from the FDA of 40 distinct incidents of adverse events associated with Renvela.® We excluded incidents where other medications may have caused the adverse event reported, resulting in five in-scope incidents. Two of the five incidents were deaths, which most likely were related to the underlying disease and not treatment with Renvela.® One of the five incidents involved intestinal obstruction and perforation, which the patient's physician thought were possibly related to the patient's treatment with Renvela.® In the two remaining incidents, one patient experienced gastroenteritis, and the other (who had asthma and chronic obstructive pulmonary disease) suffered severe breathing problems while on Renvela.® Neither of these two results likely was related to Renvela.®

2. Updated Injury Data

We updated the injury data since publication of the proposed rule. We searched the IPII, NEISS, and death certificate databases from 2000 through 2010, for incidents associated with Welchol,® Renvela,® and related drugs (*i.e.,* cholestyramine (Questran®) and colestipol (Colestid®)). We did not identify any incidents related to Renvela,® Questran,® or Colestid,® and identifed only one new Welchol®-related case. This incident occurred in July 2010, when a 19-month-old boy was found in his crib with an open Tylenol® bottle. The bottle was previously used for carrying Welchol® and other drugs. It was not clear from the report if any Welchol® tablets were in the bottle when the child accessed it. The child was taken to the emergency department, held overnight for observation, and then released the next day.

Additionally, we searched Poisindex® (a comprehensive database which identifies the toxicity of commercial, biological, and pharmaceutical products), and the medical literature for updated information on colesevelam hydrochloride and sevelamer carbonate colestipol, and cholestyramine. We found no incidents of acute poisoning in humans through this search.

3. Powder Formulations Generally

We also evaluated the likelihood of children younger than 5 years old ingesting powdered substances. The powdered form of these substances makes them more difficult to ingest than medicines in other forms and therefore, likely will keep children from ingesting significant quantities. It would be difficult for children under 5 years old to eat large amounts of powder quickly without aspirating or coughing. It also would be difficult for children to mix powder thoroughly in a liquid, and the resulting lumpy quality may be unappealing to children who try to drink it. Although children are likely to be able to tear open the non-child-resistant packets used for Welchol® and Renvela,® they are likely to spill much of the contents; therefore, they would have to open a number of packages to access a significant quantity of the drug. Most unintentional poisonings among children occur during short lapses in direct visual supervision. The difficulty posed by ingestion of powder introduces a delay in the poisoning scenario, and supervision is likely to resume before a child can take in a significant quantity.

As noted in the preamble to the proposed rule (76 FR at 8944), the packages used with the powder formulations of Welchol® and Renvela® also reduce the likelihood of child poisoning. Both drugs are provided in small, foil-lined packages containing individual doses. The Renvela® package is easy to tear only at the notch. Because the package must be opened at a precise location, it is less accessible, especially to young children. The Welchol® package does not have a notch and has uniform resistance to tearing, which makes it more difficult to open than Renvela.® Although both packages tear easily enough to be opened by children under 5 years of age, the fine motor skills of children in this age group are still developing, and such children are likely to spill most of the powder.

D. Response to Comments on the Proposed Rule

We published a notice of proposed rulemaking in the **Federal Register** on February 16, 2011, to exempt colesevelam hydrochloride (Welchol®) and sevelamer carbonate (Renvela®) from the special packaging requirements of the PPPA. 76 FR 8942. The proposed rule would amend our existing regulations at 16 CFR § 1700.14 by adding a new paragraph (a)(10)(xxii) to exempt coleselam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug. The proposed rule also would create a new paragraph (a)(10)(xxiii) to exempt sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug. We received 27 comments, with 15 supporting the proposed rule. In general, the comments did not address the codified text; instead, they focused on issues relating to the drugs themselves. The comments are available at *http://www.regulations.gov/#!docketDetail;rpp=50;po=0;D=CPSC–2011–0007*. This section summarizes the issues raised by the comments and provides responses to those issues. Each summarized issue is identified below as a single comment, and the word ''Comment,'' in parentheses, will appear before the summary description of all comments on that issue, and the word ''Response,'' in parentheses, will appear before our response to the issue. We also have numbered each summarized issue as a separate comment to help distinguish between the different issues raised by the commenters and summarized by us. They are listed in no particular order.

1. Concern About Possible Harm to Children

(Comment 1)—Some commenters were concerned about what they felt was a lack of data, and they thought that these drugs could be harmful to children (*e.g.,* cause bowel obstruction, electrolyte/serum glucose imbalance, and death), particularly if ingested in large amounts. One commenter also questioned the use of adverse effect data from adults and animals in predicting toxicity from accidental poisoning in children.

(Response 1)—We typically consider all available data in toxicity assessments, with human data taking precedence over animal data. While limited data are available on the acute toxicity of Welchol® and Renvela® in children, the adverse effects reported are similar to those in adults. Because these drugs are not absorbed

systemically, acute adverse effects typically are limited to the GI tract and are unlikely to be serious. An extension of these effects would be expected in an overdose scenario. Notably, intestinal obstruction has only been observed during therapeutic use of these drugs in patients whose health has been compromised otherwise (*e.g.,* low birth weight, chronic kidney disease, and adhesions). Cases have been documented in infants and one child following treatment with a similar drug, cholestyramine. In addition, a 45-year-old male developed an intestinal obstruction, perforation, and an abdominal fistula (abnormal opening in the stomach or bowel, which allows the contents to leak) after several months of treatment with Renvela.® Intestinal obstruction has occurred very rarely after treatment with Welchol.® In fact, Welchol ® has a greater specificity for bile acids than cholestyramine and colestipol and has been suggested to have greater gastrointestinal tolerance than the other two drugs.

Based on all available information, an imbalance of electrolytes or glucose control is unlikely to occur following an acute exposure to Welchol ® or Renvela.® No unexpected laboratory tests were seen following chronic administration of 3.75 grams g/day of Welchol ® to pediatric subjects with heterozygous familial hypercholesteremia or 15 g/day of Renvela ® to normal volunteers. Chronic administration of Welchol ® decreased fasting glucose levels 3.9–15.9 mg/dl. Because a blood glucose goal is 100–180 mg/dl for children, it is unlikely that acute administration of Welchol ® would cause hypoglycemia (*i.e.,* low blood sugar) in a child (less than 60 mg/dl).

Moreover, as discussed in section C of this preamble, there are no available poisoning data showing that these drugs cause serious toxicity following an acute exposure.

2. Questions About Powder Form

(Comment 2)—Some commenters argued that: (1) The powder may present a choking hazard to children; and (2) there is little support for claims that the powders are more difficult for children to ingest, access from the packet without spilling, and mix thoroughly in a liquid.

(Response 2)—The low acute toxicity of Welchol® and Renvela® is a key factor for the exemptions. Additionally, CPSC's Human Factors staff considered relevant data and medical literature to conclude that powders generally present a low risk because they are more difficult to ingest, particularly in large quantities. Generally, with the exception of caustics, the primary exposure risk associated with powders is aspiration. Notably, any potential choking hazard with these drugs could also occur with any non-pharmaceutical powder formulation available in the household, such as soaps, baby powder, drink mixes, and food products.

We maintain that a child would have difficulty opening the packet of either of these drugs and mixing the powder with a liquid because of the lack of precision and control required. Moreover, there are no available poisoning data with these or similar drugs (colestipol or cholestyramine) to indicate otherwise.

3. Mixing With Other Substances

(Comment 3)—One commenter stated that he believes that ''the drug can potentially be mixed with something to create an adverse reaction.''

(Response 3)—The commenter provided no evidence to suggest that this is a likely event, and no information or examples of a substance that would cause an adverse reaction when mixed with Welchol® or Renvela®. Although it is possible that a child might mix the powder with a liquid in imitation of an adult, it is highly unlikely that a child would do so repeatedly because a small child can drink only a limited amount of liquid at one time. In addition, the consistency of incompletely mixed powder is likely to deter repetition.

4. Benefits of the Exemptions

(Comment 4)—Some commenters asserted that benefits from the CR exemptions are limited: increased profits for the manufacturers of the drugs; and ease of opening the package.

(Response 4)—Exempting from CR requirements the powder forms of Welchol® and Renvela® may increase patient compliance. Poor adherence to medication regimens for chronic health issues is a well-established concern. Easier access to these drugs could benefit patients with minimal or no risk to children.

E. Effective Date

This rule exempts two drugs that otherwise would be subject to CR packaging requirements under the PPPA. Because the rule grants an exemption, it is not subject to the usual requirement under the Administrative Procedure Act (''APA'') that a rule must be published 30 days before it takes effect. 5 U.S.C. 553(d)(1). Therefore, it is appropriate for the rule to become effective upon publication in the **Federal Register**.

F. Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601 *et seq.,* an agency that engages in rulemaking generally must prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

As noted in the preamble to the proposed rule (76 FR at 8945), the Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to exempt powder formulations of Welchol® and Renvela® from special packaging requirements. Based on this assessment, we preliminarily concluded that the proposed amendment exempting powder formulations of Welchol® and Renvela® from special packaging requirements would not have a significant impact on a substantial number of small businesses or other small entities. We received no comments on this assessment or any additional information. Therefore, we conclude that exempting powder formulations of colesevelam hydrochloride (currently marketed as Welchol® and sevelamer carbonate (currently marketed as Renvela® from special packaging requirements would not have a significant impact on a substantial number of small businesses or other small entities.

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, we have assessed the possible environmental effects associated with the proposed PPPA amendment. As discussed in the preamble to the proposed rule, CPSC regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in this rule alters that expectation. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

H. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state

in clear language the preemptive effect, if any, of new regulations.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, ''no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard.'' 15 U.S.C. 1476(a). A state or local standard may be excepted from this preemptive effect if: (1) the state or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the state or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through a process specified at 16 CFR part 1061. 15 U.S.C. 1476(c)(1). In addition, the Federal government, or a state or local government, may establish and continue in effect a nonidentical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, state, or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the rule exempting powder formulations of Welchol® and Renvela® from special packaging requirements preempts nonidentical state or local special packaging standards for the substances.

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission amends 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

■ 1. The authority citation for part 1700 continues to read as follows:

Authority: 15 U.S.C. 1471–76. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

■ 2. Section 1700.14 is amended by adding paragraphs (a)(10)(xxii) and (xxiii) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(10) * * *

(xxii) Colesevelam hydrochloride in powder form in packages containing not more than 3.75 grams of the drug.

(xxiii) Sevelamer carbonate in powder form in packages containing not more than 2.4 grams of the drug.

* * * * *

Dated: July 18, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–18511 Filed 7–21–11; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 15 and 20

RIN 3038–AD17

Large Trader Reporting for Physical Commodity Swaps

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rules.

SUMMARY: The Commission is adopting reporting regulations (''Reporting Rules'') that require physical commodity swap and swaption (for ease of reference, collectively ''swaps'') reports. The new regulations require routine position reports from clearing organizations, clearing members and swap dealers and also apply to reportable swap trader positions.

DATES: *Effective Dates:* This rulemaking shall become effective September 20, 2011.

FOR FURTHER INFORMATION CONTACT: Bruce Fekrat, Senior Special Counsel, Office of the Director, (202) 418–5578, *bfekrat@cftc.gov,* or Ali Hosseini, Attorney-Advisor, Office of the Director, (202) 418–6144, *ahosseini@cftc.gov,* Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background and Summary of Comments

A. Background

On November 2, 2010, the Commission proposed Reporting Rules that, in addition to establishing recordkeeping requirements, require routine swaps position reports from clearing organizations, clearing members and swap dealers and apply non-routine reporting requirements to large swaps traders.[1] The Reporting Rules, as finalized and adopted herein, will allow the Commission to administer its regulatory responsibilities under the Commodity Exchange Act (''CEA or Act'') by implementing and conducting effective surveillance of economically equivalent physical commodity futures, options and swaps. The Reporting Rules will directly support the Commission's transparency initiatives such as its dissemination of Commitments of Traders and Index Investment Data Reports and will allow the Commission to monitor compliance with the trading requirements of the Act.[2]

The Commission currently receives and uses for market surveillance and enforcement purposes, data on large positions in all physical commodity futures and option contracts traded on designated contract markets (''DCMs''). Without the Reporting Rules, there would be no analogous reporting system in place for economically equivalent swaps, which until recently were largely unregulated financial contracts. The Reporting Rules, as discussed below, are reasonably necessary for the effective surveillance of economically equivalent futures and swaps.

B. Proposed Reporting Rules Summary of Comments

The Commission received approximately 130 comment letters, and engaged in several *ex parte* communications, for the proposed Reporting Rules. The Commission has carefully reviewed and considered the submitted comments. Substantive comments pertinent to specific provisions in the rulemaking are summarized and discussed below and in other sections of this notice.

The National Futures Association (''NFA'') submitted a comment[3] suggesting that its issuance of trader identifications should be a part of the position reporting process. Although beyond the scope of this rulemaking as proposed, the Commission may review the feasibility of adopting such an approach as a part of its ongoing updating and revision of other transaction and position reporting requirements.

The Air Transport Association (''ATA''), Better Markets Inc. (''Better Markets''), the Petroleum Marketers Association of America (''PMAA'') and New England Fuel Institute (''NEFI''), and Robert Pollin and James Heintz of the Political Economy Research Institute

[1] 75 FR 67258, November 2, 2010. Comments and *ex parte* communications list *available at http://comments.cftc.gov/PublicComments/CommentList.aspx?id=889.*

[2] *See* 76 FR 4752, January 26, 2011.

[3] Letter from Thomas W. Sexton, Senior Vice President and General Counsel, NFA, to David A. Stawick, Secretary, CFTC (December 2, 2010).