

# Proposed Rules

Federal Register

Vol. 83, No. 45

Wednesday, March 7, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2018-C-0617]

#### GW Cosmetics GmbH; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of petition.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing that we have filed a petition, submitted by GW Cosmetics GmbH, proposing that the color additive regulations be amended to provide for the safe use of silver nitrate in professional-use only cosmetics to color eyebrows and eyelashes.

**DATES:** Submit either electronic or written comments on the petitioner's environmental assessment by April 6, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 6, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 posted on <https://www.regulations.gov>.

- 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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2018-C-0617 for "GW Cosmetics GmbH; Filing of Color Additive Petition." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Laura A. Dye, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1275.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), we are giving notice that we have filed a color additive petition (CAP No. 8C0312), submitted by GW Cosmetics GmbH, c/o EAS Consulting Group, LLC, 1700 Diagonal Rd., Suite 750, Alexandria, VA 22314. The petition proposes to amend the color additive regulations in 21 CFR part 73 *Listing of Color Additives Exempt From Certification* to provide for the safe use of silver nitrate in professional-use only cosmetics to color eyebrows and eyelashes.

We are reviewing the potential environmental impact of this petition. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), we are placing the environmental assessment submitted

with the petition that is the subject of this notice on public display at the Dockets Management Staff (see **ADDRESSES**) for public review and comment.

We will also place on public display, in the Dockets Management Staff and at <https://www.regulations.gov>, any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on our review, we find that an environmental impact statement is not required, and this petition results in a regulation, we will publish the notice of availability of our finding of no significant impact and the evidence supporting that finding with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: March 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-04619 Filed 3-6-18; 8:45 am]

**BILLING CODE 4164-01-P**

## PENSION BENEFIT GUARANTY CORPORATION

**29 CFR Parts 4001, 4022, 4041, 4043, and 4044**

**RIN 1212-AB24**

### Owner-Participant Changes to Guaranteed Benefits and Asset Allocation

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Proposed rule.

**SUMMARY:** The Pension Benefit Guaranty Corporation (PBGC) proposes to amend its regulations on guaranteed benefits and asset allocation. These amendments would incorporate statutory changes to the rules for participants with certain ownership interests in a plan sponsor. PBGC seeks public comment on its proposal.

#### **DATES:**

*Deadline for comments:* Comments must be submitted on or before May 7, 2018.

*Applicability:* Like the provisions of the Pension Protection Act of 2006 (PPA 2006) that this rule would incorporate, the amendments in this proposed rule would be applicable to plan terminations—

(A) under section 4041(c) of the Employee Retirement Income Security Act of 1974 (ERISA) with respect to which notices of intent to terminate are provided under section 4041(a)(2) of ERISA after December 31, 2005, and

(B) under section 4042 of ERISA with respect to which notices of determination are provided under that section after December 31, 2005.

**ADDRESSES:** Comments, identified by Regulation Identifier Number (RIN) 1212-AB24, may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. (Follow the online instructions for submitting comments.)
- *Email:* [reg.comments@pbgc.gov](mailto:reg.comments@pbgc.gov).
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026.

All submissions must include the RIN for this rulemaking (RIN 1212-AB24). Comments received will be posted to [www.pbgc.gov](http://www.pbgc.gov). Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026, or calling 202-326-4040 during normal business hours. (TTY users may call the Federal relay service toll-free at 800-877-8339 and ask to be connected to 202-326-4040.)

#### **FOR FURTHER INFORMATION CONTACT:**

Samantha M. Lowen ([lowen.samantha@pbgc.gov](mailto:lowen.samantha@pbgc.gov)), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005-4026; 202-326-4400, extension 3786. (TTY and TDD users may call the Federal relay service toll-free at 800-877-8339 and ask to be connected to 202-326-4400, extension 3786.)

#### **SUPPLEMENTARY INFORMATION:**

##### **Executive Summary**

##### *Purpose of the Regulatory Action*

This proposed rule is necessary to conform the regulations of PBGC to current law and practice. PBGC proposes to incorporate statutory changes affecting guaranteed benefits and asset allocation when a plan has one or more participants with certain ownership interests in the plan sponsor. PBGC's legal authority for this action comes from sections 4002(b)(3), 4022, and 4044 of ERISA. Section 4002(b)(3) authorizes PBGC to issue regulations to carry out the purposes of title IV of ERISA. Sections 4022 and 4044 authorize PBGC to prescribe regulations regarding the determination of guaranteed benefits and the allocation of assets within priority categories, respectively.

##### *Major Provisions*

This proposed rule would amend PBGC's benefit payment regulation by replacing the guarantee limitations applicable to substantial owners with a new limitation applicable to majority owners.<sup>1</sup> Additionally, this proposed rule would amend PBGC's asset allocation regulation by prioritizing funding of all other benefits in priority category 4 ahead of those benefits that would be guaranteed but for the new, owner-participant limitation. The proposed rule also clarifies that plan administrators may continue to use the simplified calculation in the existing rule to estimate benefits funded by plan assets. Finally, it provides new examples to aid in implementation.

##### **Background**

PBGC administers the pension insurance program under title IV of ERISA. ERISA sections 4022 and 4044 cover PBGC's guarantee of plan benefits and allocation of plan assets, respectively, under terminated single-employer plans. Special provisions within these sections apply to "owner-participants," who have certain ownership interests in their plan sponsors. PPA 2006 made changes to these provisions. PBGC has been operating in accordance with the amended provisions since they became effective, but has not yet updated its regulations nor issued guidance on implementation. With this rulemaking, PBGC intends to increase transparency into its operations and to clarify for plan administrators the impact of the statutory changes.

Before PPA 2006, the owner-participant provisions applied to any participant who was a "substantial owner" at any time within the 60 months preceding the date on which the determination was made. ERISA defines a substantial owner as an individual who owns the entire interest in an unincorporated trade or business, or a partner or shareholder who owns more than 10 percent of the partnership or corporation. PPA 2006 revised the owner-participant provisions, in large part, by making them applicable to "majority owners" instead of substantial owners. ERISA defines a majority owner as an individual who owns the entire interest in an unincorporated trade or business, or a partner or shareholder who owns 50 percent or more of the entity.

<sup>1</sup> In this preamble, substantial owners and majority owners are referred to interchangeably as "owner-participants."