PART 232—REGULATION S–T—
GENERAL RULES AND REGULATIONS
FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77k(a), 77z–3, 77zss(a), 78(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 60a–6(c), 60a–8, 60a–29, 80a–30, 80a–37, and 7201 et seq.; and 18 U.S.C. 1350.

2. Section 232.301 is revised to read as follows:


Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: “General Information,” Version 25 (December 2016). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 39 (December 2016). Additional provisions applicable to Form N-SAR filers are set forth in the EDGAR Filer Manual, Volume III: “N-SAR Supplement,” Version 5 (September 2015). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is https://www.sec.gov/info/edgar/edmanual.htm. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

By the Commission

Dated: December 9, 2016.
Brent J. Fields,
Secretary.

[FR Doc. 2016–32032 Filed 1–19–17, 8:45 am]
BILLING CODE 8011–01–P

DELAWARE RIVER BASIN
COMMISSION

18 CFR Part 401

Regulatory Program Fees; Correction

AGENCY: Delaware River Basin Commission.

ACTION: Correcting amendments.

SUMMARY: The Delaware River Basin Commission published a document in the Federal Register on December 29, 2016 (81 FR 95860), in relevant part amending the Rules of Practice and Procedure. The document failed to include rule text approved by the Commission relating to the annual monitoring and coordination fee. This document corrects the final regulations by incorporating the approved language. In addition, this document corrects the preamble to clarify that in adopting the final rule, the Commission acted by Resolution No. 2016–9, not 2016–8.

DATES: This final rule is effective January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Pamela M. Bush, Commission Secretary and Assistant General Counsel, 609–477–7203.

SUPPLEMENTARY INFORMATION:

Background. When the Commission adopted Resolution No. 2016–9, in relevant part approving amendments to the Rules of Practice and Procedure (18 CFR part 401) concerning regulatory program fees, it approved rule language to expressly exclude from the calculation of the annual monitoring and coordination fee all water for which an entitlement issued pursuant to the Basin Regulations—Water Supply Charges (18 CFR part 420) is in effect. Final rule documents posted on the Commission’s Web site included the approved language, but the language was inadvertently omitted from DRBC’s Federal Register submission and thus from the CFR.

In addition, the preamble to the final rule published in the Federal Register incorrectly referred to the Commission’s rule adoption resolution as number 2016–9, when the resolution was number 2016–8.

Corrections

Preamble Correction. In final rule FR Doc. 2016–31146, beginning on page 95860 in the issue of December 29, 2016, “2016–8” is corrected to read “2016–9” in the following locations in the SUPPLEMENTARY INFORMATION section: On page 95860 in the second column (first line of the last paragraph) and third column (sixth line from the bottom); and on page 95861 in the first column (first line).

Rule Correction. As published, the final regulations omit language adopted by the Commission in response to comments received. The regulations are thus incorrect and in need of amendment, as set forth below.

List of Subjects in 18 CFR Part 401

Administrative practice and procedure, Project review, Water pollution control, Water resources.

Accordingly, 18 CFR part 401 is corrected by the following correcting amendments:

PART 401—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for part 401 continues to read as follows:

Authority: Delaware River Basin Compact (75 Stat. 688), unless otherwise noted.

Subpart C—Project Review Under Section 3.8 of the Compact

2. In § 401.43, revise paragraph (b)(2) to read as follows:

§ 401.43 Regulatory program fees.

(b) * * * * *

(2) Annual monitoring and coordination fee. (i) Except as provided in paragraph (b)(2)(ii) of this section, an annual monitoring and coordination fee shall apply to each active water allocation or wastewater discharge approval issued pursuant to the Compact and implementing regulations, regardless of whether the approval was issued by the Commission in the form of a docket, permit or other instrument, or by a Signatory Party Agency under the One Permit Program rule (§ 401.42).

The fee shall be based on the amount of a project’s approved monthly water allocation and/or approved daily discharge capacity.

(ii) For any withdrawal or diversion covered in part by a certificate of entitlement issued pursuant to §§ 420.31 and 420.32 of the water supply charges regulations (18 CFR part 420), the annual monitoring and coordination fee shall be based on the allocated amount, if any, in excess of the quantity specified in the entitlement.
Social Security Administration

20 CFR Part 404
[Docket No. SSA—2014–0016]
RIN 0960–AH66

Unsuccessful Work Attempts and Expedited Reinstatement Eligibility; Correction

AGENCY: Social Security Administration.

ACTION: Final rules; correction.

SUMMARY: We published a document in the Federal Register revising our rules on October 17, 2016. That document inadvertently omitted a corresponding technical change to §404.1592(a) when §404.1592c(a) was amended with the final rule publication. By making this technical correction we will also need to redesignate the amendatory instructions to incorporate the missing section changes to §404.1592f(a). This document corrects the final regulation by making these technical corrections.

DATES: The corrections are effective April 17, 2017.

FOR FURTHER INFORMATION CONTACT: Kristine Erwin-Tribbitt, Office of Retirement and Disability Policy, Office of Research, Demonstration, and Employment Support, Social Security Administration, 6401 Security Boulevard, Robert Ball Building 3–A–26, Baltimore, MD 21235–6401, (410) 965–3353. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at http://www.socialsecurity.gov.

SUPPLEMENTARY INFORMATION: We published a final rule in the Federal Register of October 17, 2016 (81 FR 71367) titled, Unsuccessful Work Attempts and Expedited Reinstatement Eligibility. The final rule, among other things, amended 20 CFR parts 404 and 416. We inadvertently omitted a corresponding technical change to §404.1592(a) when §404.1592c(a) was amended with the final rule publication. This document amends and corrects the final regulation.

(Catalog of Federal Domestic Assistance Program Nos. 9601, Social Security—Disability Insurance; 96.006, Supplemental Security Income; 96.008, Social Security—Work Incentives Planning and Assistance Program.)

In FR Doc. 2016–24873 appearing on page 71369 in the Federal Register of Monday, October 17, the following corrections are made:

Corrections

1. On page 71369, in the third column, redesignate amendatory instructions 6 through 9 as 7 through 10 and add new amendatory instruction 6 to read as follows:

■ 6. Amend §404.1592f by revising paragraph (a) to read as follows:

§404.1592f How do we determine reinstated benefits?

(a) If you meet the requirements for reinstatement under §404.1592c(a), we will then consider in which month to reinstate your entitlement. We will reinstate your entitlement with the earliest month, in the 12-month period that ends with the month before you filed your request for reinstatement, that you would have met all of the requirements under §404.1592c(a) if you had filed your request for reinstatement in that month. Otherwise, you will be entitled to reinstated benefits beginning with the month in which you filed your request for such benefits if you did not perform substantial gainful activity in that month. If you performed substantial gainful activity in the month of filing, but are no longer able to perform substantial gainful activity, we will reinstate your benefits with the month after the month you filed your request for reinstatement. We cannot reinstate your entitlement for any month prior to January 2001.

* * * * *

Caroline W. Colvin,
Acting Commissioner of Social Security

[FR Doc. 2017–00076 Filed 1–19–17, 8:45 am]

BILLING CODE 4191–02–P

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 73 and 74
[Docket No. FDA–2016–F–0821]

Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2–)] Copper; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 2, 2016, for the final rule that appeared in the Federal Register of November 1, 2016, and that amended the color additive regulations to provide for the safe use of titanium dioxide and [phthalocyaninato (2–)] copper to color orientation marks for intraocular lenses (IOLs). We are taking this action to ensure clarity that the effective date in the final rule remains December 2, 2016.

DATES: Effective date of final rule published in the Federal Register of November 1, 2016 (81 FR 75689), confirmed: December 2, 2016.


SUPPLEMENTARY INFORMATION: In the Federal Register of November 1, 2016 (81 FR 75689), we amended the color additive regulations in §73.3126 (21 CFR 73.3126) and §74.3045 (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2–)] copper to color orientation marks for IOLs.

The preamble to the final rule stated that persons who would be adversely affected by one or more provisions in the final rule could file electronic or written objections (81 FR 75689 at 75691). We also stated that the effective date of the final rule would be on December 2, 2016, unless a person properly files an objection or request for a hearing to review any provisions in the final rule (81 FR 75689). We explained that, to file an objection, a person must, among other things, specify with particularity the provision(s) of the regulation to which they object and the grounds for the objection (81 FR 75689 at 75691). Within each objection, a person also must specifically state whether he/she requests a hearing. We received no objections or requests for a hearing on the final rule that met these requirements. We received five general comments, including one that disagreed with the rule, but the comments did not meet the requirements to be considered an objection under 21 CFR 12.22(a)(3). Therefore, we find that the effective date of the final rule that published in the Federal Register of November 1, 2016, should be confirmed.

List of Subjects

21 CFR Part 73
Color additives, Cosmetics, Drugs, Medical devices.
DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Rin 2120-AK95

Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers; Related Aircraft Amendment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; Correction.

SUMMARY: The FAA is correcting a final rule published on December 16, 2016. In that final rule, which becomes effective on January 17, 2017, the FAA will allow air carriers to seek a deviation from the flight simulation training device (FSTD) requirements for related aircraft proficiency checks. As a result, that rule will eliminate an inconsistency that currently permits carriers that have obtained FAA approval to modify the FSTD requirements for related aircraft differences training, but not for corresponding proficiency checks. The FAA inadvertently listed an incorrect Amendment Number for that final rule. This document corrects that error.


FOR FURTHER INFORMATION CONTACT: Sheri Pippin, Air Transportation Division, APS-200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-8166; email sheri.pippin@faa.gov.

SUPPLEMENTARY INFORMATION:

Background. On December 16, 2016, the FAA published a final rule entitled, "Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers; Related Aircraft Amendment.” 81 FR 90979. In that final rule, effective January 17, 2017, the FAA inadvertently listed the incorrect Amendment Number for part 121 in the header information of the final rule as 121-397. The correct amendment number is 121-377.

Correction

In the final rule, FR Doc. 2016-30211, published on December 16, 2016, at 81 FR 90979 make the following correction:

On page 90979 in the heading of the final rule, revise “Amdt. No. 121-397” to read as “121-377”.

Issued in Washington, DC, under the authority provided by 49 U.S.C. 106(f), on December 22, 2016.

Lirio Liu, Director, Office of Rulemaking

[FR Doc. 2016-31507 Filed 12-28-16, 8:45 am]

BILLING CODE 4910-13-P

DELAWARE RIVER BASIN COMMISSION

18 CFR Parts 401 and 420

Regulatory Program Fees and Water Supply Charges

AGENCY: Delaware River Basin Commission.

ACTION: Final rule.

SUMMARY: The Commission amends the Rules of Practice and Procedure and the Basin Regulations—Water Supply Charges, respectively, to adopt a new project review fee structure and provide for automatic inflation adjustments. These changes are also incorporated into the Commission’s Comprehensive Plan.

DATES: This final rule is effective January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Richard C. Gore, Director of Administration and Finance, 609-883-9500, ext. 201.

SUPPLEMENTARY INFORMATION:

Background. The Delaware River Basin Commission (“DRBC” or “Commission”) is a Federal-interstate compact agency charged with managing the water resources of the Delaware River Basin on a regional basis without regard to political boundaries. Its members are the governors of the four basin states—Delaware, New Jersey, New York and Pennsylvania—and on behalf of the federal government, the North Atlantic Division Commander of the U.S. Army Corps of Engineers.

By Resolution No. 2016-8 on December 14, 2016 the Commission approved a comprehensive revision of its project review fee structure, including an automatic annual indexed inflation adjustment for most fees. An inflation adjustment was also approved for DRBC’s water supply charges rates applicable to consumptive and non-consumptive surface water withdrawals. The changes to DRBC’s regulatory program fees are designed to provide a more predictable and sustainable source of revenues and to close the annual gap in funding needed to support DRBC’s project review program. They also adjust the fees program to better align with the One Process/One Permit Program instituted earlier in 2016. The changes to DRBC’s water supply charges regulations are designed to help revenues assigned to DRBC’s Water Supply Storage Facilities Fund keep pace with inflation.

Public Process. A Notice of Proposed Rulemaking and Public Hearing was posted to the Commission’s Web site on May 9, 2016. A detailed set of questions and answers about the proposal (“FAQs”) and a press release accompanied the May 9, 2016 web posting. On May 10, 2016, an email alert, including a link to the notice and supporting documents, was transmitted to all parties subscribed to DRBC’s list serve. Notice of the proposed rules was published in the Federal Register at 81 FR 35662, June 3, 2016 and appeared in the Delaware Register of Regulations, 19 DE Reg., 1052, June 1, 2016; New Jersey Register, 48 N.J.R. 949, June 6, 2016; New York State Register, May 25, 2016 (page 1); and Pennsylvania Bulletin, 46 Pa.B. 2967, June 11, 2016. DRBC staff hosted a public informational meeting on the proposal on Wednesday, June 15, 2016 in Washington Crossing, Pa., including presentations by staff and informal questions and answers. The FAQs posted on the Commission’s Web site were thereafter supplemented with questions and responses offered during the informational meeting. A public hearing on the proposed amendments took place at the Commission’s office building in West Trenton, N.J. on July 27, 2016 and written comments were accepted through August 12, 2016.

In response to the written and oral comments submitted on the draft rules, staff developed a detailed comment and response document, including modest changes to the rule text. After careful consideration and consultation with staff on the comments and proposed changes to the draft rules, the Commissioners determined that the changes were appropriate, responsive to the public’s concerns and a logical outgrowth of the rules as proposed. The changes and the staff response to comments were adopted by unanimous vote of the Commissioners to approve Resolution No. 2016–8 at the Commission’s public business meeting on December 14, 2016.

Additional materials. The following additional materials can be found on the Commission’s Web site: www.drbc.net:
§ 401.43 Regulatory program fees.

The purpose of this section is to provide an adequate, stable and reliable stream of revenue to cover the cost of the Commission’s regulatory program activities, an important means by which the Commission coordinates management of the shared water resources of the Basin. Activities to be covered by the fees include the review of applications for projects that are subject to review under the Delaware River Basin Compact and implementing regulations; and ongoing activities associated with such projects, including but not limited to, effluent and ambient monitoring, data analysis, hydrodynamic and water quality modeling, and coordination with state and federal agencies.

(a) Purpose. The purpose of this section is to provide an adequate, stable

(b) Types of fees. The following types of fees are established by this section:

(i) Docket application fee. Except as set forth in paragraph (b)(1)(ii) of this section, the docket application fee shall apply to:

(A) Any project for which the Delaware River Basin Compact and DRBC regulations, requires a Commission-issued docket or permit, whether it be a new or existing project for which the Commission has not yet issued an approval or a project for which the renewal of a previous Commission approval is required.

(B) Any project for which the renewal of a previous Commission approval is required.

(ii) Project requiring inclusion in the comprehensive plan. Any project that in accordance with section 13.1 of the Delaware River Basin Compact and DRBC regulations must be added to the Comprehensive Plan (also, “Plan”), in addition to any new project required to be included in the Plan, such projects include existing projects that in accordance with section 13.1 of the Compact are required to be included in the Plan and which were not previously added to the Plan. Any existing project that is changed substantially from the project as described in the Plan shall be deemed to be a new and different project for purposes of this section.

(iii) Exemptions. The docket application fee shall not apply to:

(A) Any project for which the Signatory Party Agency serves as lead under the One Permit Program rule (§ 401.42), unless such project must be added by the Commission to the Comprehensive Plan.

(B) Any project for which an agency, authority or commission of a signatory to the Compact is the primary sponsor. Projects sponsored by political subdivisions of the signatory states shall not be included in this exemption. For purposes of this section “political subdivisions” shall include without limitation, municipalities, municipal utility authorities, municipal development corporations, and all other entities not directly under the budget and administrative control of the Commission’s members.

(2) Annual monitoring and coordination fee. An annual monitoring and coordination fee shall apply to each withdrawal and/or discharge project for which a water allocation or wastewater discharge approval issued pursuant to the Compact and implementing regulations is in effect, regardless of whether the approval was issued by the Commission in the form of a docket, permit or other instrument, or by a Signatory Party Agency under the One Permit Program rule (§ 401.42). The fee shall be based on the amount of a project’s approved monthly water allocation and/or approved daily discharge capacity.

(3) Alternative review fee. In instances where the Commission’s activities and related costs associated with the review of an existing or proposed project are expected to involve extraordinary time and expense, an alternative review fee equal to the Commission’s actual costs may be imposed. The Executive Director shall inform the project sponsor in writing when the alternative review fee is to be applied and may require advance payment in the amount of the Commission’s projected costs. Instances in which the alternative review fee may apply include, but are not limited to, matters in which:

(i) DRBC staff perform a detailed pre-application review, including but not limited to the performance or review of modeling and/or analysis to identify target limits for wastewater discharges.

(ii) DRBC staff perform or review complex modeling in connection with the design of a wastewater discharge diffuser system.

(iii) DRBC manages a public process for which the degree of public involvement results in extraordinary effort and expense, including but not limited to, costs associated with multiple stakeholder meetings, special public hearings, and/or voluminous public comment.

(iv) DRBC conducts or is required to engage third parties to conduct additional analyses or evaluations of a project in response to a court order.

(4) Additional fees—(i) Emergency approval. A request for an emergency certificate under § 401.40 to waive or amend a docket condition shall be subject to a minimum fee in accordance with paragraph (e) of this section. An alternative review fee also may be charged in accordance with paragraph (b)(3) of this section.

(ii) Late filed renewal application. Any renewal application submitted
fewer than 120 calendar days in advance of the expiration date or after such other date specified in the docket or permit or letter of the Executive Director for filing a renewal application shall be subject to a late filed renewal application charge in excess of the otherwise applicable fee.

(iii) Modification of a DRBC approval. Following Commission action on a project, each project revision or modification that the Executive Director deems substantial shall require an additional docket application fee calculated in accordance with paragraph (e) of this section and subject to an alternative review fee in accordance with paragraph (b)(3) of this section.

(iv) Name change. Each project with a docket or permit issued by the DRBC or by a Signatory Party Agency pursuant to the One Permit Program rule

(§ 401.42) will be charged an administrative fee as set forth in paragraph (e) of this section.

(v) Change of ownership. Each project that undergoes a “change in ownership” as that term is defined at 18 CFR 420.31(e)(2) will be charged an administrative fee as set forth in paragraph (e) of this section.

(c) Indexed adjustment. On July 1 of every year, beginning July 1, 2017, all fees established by this section will increase commensurate with any increase in the annual April 12-month Consumer Price Index (CPI) for Philadelphia, published by the U.S. Bureau of Labor Statistics during that year. In any year in which the April 12-month CPI for Philadelphia declines or shows no change, the docket application fee and annual monitoring and coordination fee will remain unchanged. Following any indexed adjustment made under this paragraph (c), a revised fee schedule will be published in the Federal Register by July 1 and posted on the Commission’s Web site. Interested parties may also obtain the fee schedule by contacting the Commission directly during business hours.

(d) Late payment charge. When any fee established by this section remains unpaid 30 calendar days after the payment due date provided on the Commission’s invoice, an incremental charge equal to 2% of the amount owed shall be automatically assessed. Such charge shall be assessed every 30 days thereafter until the total amount owed, including any late payment charges, has been paid in full.

(e) Fee schedules. The fees described in this section shall be as follows:

<table>
<thead>
<tr>
<th>TABLE 1 TO § 401.43—DOCKET APPLICATION FILING FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project type</td>
</tr>
<tr>
<td>Water Allocation ...............</td>
</tr>
<tr>
<td>Wastewater Discharge ............</td>
</tr>
<tr>
<td>Other .............</td>
</tr>
</tbody>
</table>

\(^1\) Subject to annual adjustment in accordance with paragraph (c) of this section.

<table>
<thead>
<tr>
<th>TABLE 2 TO § 401.43—ANNUAL MONITORING AND COORDINATION FEE</th>
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</thead>
<tbody>
<tr>
<td>Project type</td>
</tr>
<tr>
<td>Annual fee</td>
</tr>
<tr>
<td>Water Allocation ...............</td>
</tr>
<tr>
<td>Wastewater Discharge ............</td>
</tr>
</tbody>
</table>

\(^1\) Subject to annual adjustment in accordance with paragraph (c) of this section.

<table>
<thead>
<tr>
<th>TABLE 3 TO § 401.43—ADDITIONAL FEES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed action</td>
</tr>
<tr>
<td>Emergency Approval Under 18 CFR 401.40</td>
</tr>
<tr>
<td>Late Filed Renewal Surcharge .......</td>
</tr>
<tr>
<td>Modification of a DRBC Approval ....</td>
</tr>
<tr>
<td>Name change ....</td>
</tr>
<tr>
<td>Change of Ownership ................</td>
</tr>
</tbody>
</table>

\(^1\) Subject to annual adjustment in accordance with paragraph (c) of this section.

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\(^1\) Consumer Price Index—\(U/Series\) \(ID:\) CWURA102SA00/Not Seasonally Adjusted/Area Philadelphia-Wilmington-Atlantic City, PA-NJ-DE-MD/Item All items/Base Period: 1982-84 = 100.
PART 420—BASIN REGULATIONS—WATER SUPPLY CHARGES

§ 420.41 Schedule of water charges.

The schedule of water charges established in accordance with § 420.22 shall be as follows:

(a) $0.80 per million gallons for consumptive use, subject to paragraph (c) of this section; and

(b) $0.80 per million gallons for non-consumptive use, subject to paragraph (c) of this section.

(c) On July 1 of every year, beginning July 1, 2017, the rates established by this section will increase commensurate with any increase in the annual April 12-month Consumer Price Index (CPI) for Philadelphia, published by the U.S. Bureau of Labor Statistics during that year. In any year in which the April 12-month CPI for Philadelphia declines or shows no change, the water charges rates will remain unchanged. Following any indexed adjustment made under this paragraph (c), revised consumptive and non-consumptive use rates will be published in the Federal Register by July 1 and posted on the Commission’s Web site. Interested parties may also obtain the rates by contacting the Commission directly during business hours.

Dated: December 20, 2016.

Pamela M. Bush,
Commission Secretary
[FR Doc. 2016-31146 Filed 12-23-16; 4:15 pm]
BILLING CODE 6380-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105
[Docket No. FDA—2016–N–1555]

Refuse To Accept Procedures for Premarket Tobacco Product Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule describing when FDA will refuse to accept a tobacco product submission (or application) because the application has not met a minimum threshold for acceptability for FDA review. Under the rule, FDA will refuse to accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. By refusing to accept submissions that have the deficiencies identified in the proposed rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions.

DATES: This rule is effective January 30, 2017.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Paul Hart, Office of Regulations, Center for Tobacco Products (CTP), Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Rule

FDA is issuing this rule to identify deficiencies that will result in FDA’s refusal to accept certain tobacco product submissions under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (21 U.S.C. 387e, 387j, and 387k). Because these submissions will be refused before they enter FDA’s review queue, more resources will be available for submissions that are ready for further review. This rule establishes a refuse to accept process for premarket tobacco product submissions, including premarket tobacco product applications (PMTAs), modified risk tobacco product applications (MRTPAs), substantial equivalence (SE) applications (also called SE reports), and exemption requests (including subsequent abbreviated reports).

B. Summary of the Major Provisions of the Regulatory Action

The rule explains when FDA will refuse to accept a premarket submission, including PMTAs, MRTPAs, SE applications, and exemption requests (including subsequent abbreviated reports). The rule is based on FDA’s experience in reviewing these submissions. Under the rule, FDA will refuse to accept a premarket submission that: (1) Does not pertain to a tobacco product; (2) is not in English (or does not include a complete translation); (3) is submitted in an electronic format that FDA cannot process, read, review, or archive; (4) does not include the applicant’s contact information; (5) is from a foreign applicant and does not include the name and contact information of an authorized U.S. agent (authorized to act on behalf of the applicant for the submission); (6) does not include a required form(s); (7) does not identify the tobacco product; (8) does not identify the type of submission; (9) does not include the signature of a responsible official authorized to represent the applicant; or (10) does not include an environmental assessment or claim of a categorical exclusion, if applicable. Under the rule, if FDA refuses to accept a submission, FDA will send the contact (if available) a notification. If the submission is accepted for further review, FDA will send an acknowledgement letter.

II. Background

FDA published two rulemaking documents concerning refuse to accept procedures in the Federal Register of August 8, 2016: A direct final rule (81 FR 52329) and a companion proposed rule (81 FR 52371). We published the direct final rule because we believed that the rule was noncontroversial, and we did not anticipate that it would receive any significant adverse comments. As a companion to the direct final rule, we published a proposed rule with the same codified language published in the proposed rules section of the Federal Register. The companion proposed rule provides a procedural framework to finalize the rule in the event that the direct final rule receives any adverse comment and is withdrawn. We received adverse comment on the direct final rule and withdrew the direct final rule by issuing a notice in the Federal Register of November 16, 2016 (81 FR 60567). We are now finalizing the proposed rule and responding to the comments we received.