two be combined by creating a Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities form. By combining the forms, P&As will have a reduced burden because they will only have to submit one annual report. The combined form will also allow federal reviewers to analyze patterns more readily between goals and priority setting and program performance.

The annual PPR and SGP are reviewed by federal staff for compliance and outcomes. Information in the PPRs and SGPs is analyzed to create a national profile of programmatic compliance, outcomes, and goals and priorities for P&A Systems for tracking accomplishments against goals and to formulate areas of technical assistance related to compliance with Federal requirements and program performance. Information collected in the unified report will inform AIDD of trends in P&A advocacy, collaboration with other federally-funded entities, and identify best practices for efficient use of federal funds.

Comments in Response to the 60 Day Federal Register Notice

A notice was published in the **Federal Register** in Vol. 81, No. 57592 on August 23, 2016, announcing that ACL was requesting approval of a data collection (ICR New). ACL received two comments expressing concern that the combination of the SGP and PPR reporting forms would reduce the overall oversight of the P&A program. ACL responds that, while the reporting forms are being combined, the content which the grantees are reporting remains the same, with the addition of more quantitative measures to support the qualitative data that the grantees provide every year. The addition of more quantitative measures will provide a fuller picture of how the programs are functioning. The combined PPR and SGP allow federal staff to review the same information from the programs in a streamlined format that reduces the need to reenter the same information multiple times. ACL does not plan to make any changes in the data collection based on these comments.

SUPPLEMENTARY INFORMATION: In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration on Community Living is soliciting public comment on the burden related to the information collection described above. *The form is available at: http://www.acl.gov/Programs/AIDD/Program_Resource_Search/Results_PA.aspx.*

Estimated Burden: The average burden for the 57 Protection and Advocacy Systems [i] was calculated based on consultations with selected States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy Annual Program Performance Report and Statement of Goals and Priorities	57	1	75	4,275

Estimated Total Annual Burden Hours: 4,275.

Dated: January 10, 2017.

Edwin L. Walker,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–00880 Filed 1–13–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4412]

Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an Abbreviated New Drug Application; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.'' This draft guidance is intended to assist potential applicants who plan to develop and submit an abbreviated new drug application (ANDA) to seek approval of a generic combination product that includes both a drug constituent part and a delivery device constituent part.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance March 20, 2017.

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 posted on *http://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):* Division of Dockets Management (HFA–305), Food

[i] This number includes the 50 States, District of Columbia, Puerto Rico and three Outlying Areas.

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, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–4412 for ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *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/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Andrew LeBoeuf, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0503, *Andrew.LeBoeuf@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.''

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) created, among other things, section 505(j) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Under section 505(j) of the FD&C Act, an ANDA applicant can rely on FDA's previous finding that the reference listed drug (RLD) is safe and effective so long as the ANDA applicant demonstrates that the proposed drug product and the RLD are the same with respect to active ingredient(s), dosage form, route of administration, strength, and, with certain exceptions, labeling. An ANDA must also include sufficient information to demonstrate that the proposed product is bioequivalent to the RLD, and that the ANDA meets the approval requirements relating to chemistry, manufacturing, and controls. An ANDA generally is not required to be the same as the listed drug it references in certain respects. For example, a generic drug generally can differ from its RLD in certain respects with regard to the device or with respect to inactive ingredients.

Drug products that meet the approval requirements under section 505(j) of the FD&C Act are generally considered by FDA to be therapeutically equivalent to their RLD. Products classified as therapeutically equivalent can be substituted with the full expectation that the generic product will produce the same clinical effect and safety profile as the RLD under the conditions specified in the labeling.

These general principles apply to products submitted in ANDAs, including drug-device combination products. A generic drug-device combination product classified as therapeutically equivalent to the RLD can be expected to produce the same clinical effect and safety profile as the RLD under the conditions specified in labeling. This does not mean, however, that the proposed generic drug-device combination product and its RLD need to be identical in all respects. FDA recognizes that an identical design may not always be feasible and, in certain instances, differences in the design of the user interface for a generic drug-device combination product as compared to the RLD may exist without precluding approval of the generic combination drug-device product under an ANDA. In some instances in which differences exist, certain additional information and/or data relating to the user-interface of the proposed generic drug-device combination product, such as data from comparative use human factors studies, may be appropriate to support approval of the proposed product in an ANDA. The extent to which differences between the proposed product and the RLD affect the approvability of the proposed ANDA product will be evaluated on a case-by-case basis.

This draft guidance provides general principles, including recommendations on threshold analyses, which are intended to assist potential applicants in the identification and the assessment of differences in the design of the user interface of a proposed generic drug-device combination product when compared to the user interface for its RLD.

This draft guidance also provides recommendations on the design and conduct of comparative use human factors studies that may help applicants determine whether design differences identified between the proposed generic drug-device combination product and its RLD would preclude approval as an ANDA under the FD&C Act.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA.'' It does not establish any rights for any

person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00795 Filed 1–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0121]

Compliance Policy for Required Warning Statements on Small-Packaged Cigars; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Compliance Policy for Required Warning Statements on Small-Packaged Cigars.'' The draft guidance, when finalized, is intended to assist any person who manufacturers, packages, sells, offers to sell, distributes, or imports cigars in small packages, in complying with the warning statement requirements in FDA's regulations deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance describes FDA's compliance policy for cigars in packaging that is too small or otherwise unable to accommodate a label with sufficient space to bear the required warning statements. The draft guidance explains that FDA does not intend to take enforcement action with respect to cigars that do not comply with the size and placement requirements in the regulation when the information and specifications required under the regulation appear on the carton or other outer container or wrapper that could accommodate the required warning statements, or on a tag otherwise firmly and permanently affixed to the cigar package.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2017.

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 posted on *http://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):* 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, marked and identified, as confidential, if submitted as detailed in ''instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0121 for ''Compliance Policy for Required Warning Statements on Small-Packaged Cigars.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *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/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Deirdre Jurand, Center for Tobacco