TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New requests to be placed on the lists	2,000	1	2,000	1	2,000
Biennial update	2,000	1	2,000	0.5 (30 minutes)	1,000
Occasional updates	200	1	200	0.5 (30 minutes)	100
Total					3,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. This collection is also incorporating information collected to maintain lists of eligible exporters of dairy products who wish to export to the EU from OMB control number 0910–0320, ''Request for Information from U.S. Processors that Export to the European Community.''

FDA estimates that 2,000 firms will average 60 minutes (1 hour) to submit new requests for inclusion on the list, 2,000 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 200 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system. We also believe that submission via the electronic registry system will not affect the burden estimates. An electronic registry will enhance the ability of firms to more efficiently request inclusion on export lists. FDA calculates, therefore, that the total burden for this collection is 3,100 hours ((2,000 × 1) plus (2,000 × 0.5) plus (200 × 0.5)).

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21212 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5767]

Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid Origin; Draft Guidance for Industry; Availability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 ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the FDA an abbreviated new drug application (ANDA) to seek approval to market a generic version of a previously approved drug product. This draft guidance is intended to assist potential applicants in determining when an application for a synthetic peptide drug product (specifically glucagon, liraglutide, nesiritide, teriparatide, and teduglutide) that refers to a previously approved peptide drug product of recombinant deoxyribonucleic acid (rDNA) origin should be submitted as an ANDA rather than as new drug application (NDA).

DATES: Submit either electronic or written comments on the draft guidance by December 4, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2017–D–5767 for ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' Received comments 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: Gail Schmerfeld, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1672, Silver Spring, MD 20993–0002, 301–796–9291.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin.'' In general, for FDA to approve an ANDA submitted under section 505(j) of the FD&C Act, an ANDA applicant must demonstrate, among other things, that the proposed generic drug has the ''same'' active ingredient(s) as and is bioequivalent to its reference listed drug, and that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the proposed generic drug are adequate to assure and preserve its identity, strength, quality, and purity (sections 505(j)(2)(A) and (4) (21 U.S.C. 355(j)(2)(A) and (4)) of the FD&C Act). If a person is seeking approval of a synthetic peptide drug product (specifically glucagon, liraglutide, nesiritide, teriparatide, or teduglutide) and intends to submit an application that refers to a previously approved peptide drug product of rDNA origin, if the active ingredient in the proposed synthetic peptide drug product can be shown to be the same as the active ingredient in the peptide drug product of rDNA origin, whether the application should be submitted as an ANDA under section 505(j) of the FD&C Act or as a new drug application under section 505(b) of the FD&C Act will depend largely on the impurity profile for the synthetic peptide drug product as compared to the impurity profile for the peptide drug product of rDNA origin. Differences in impurities, particularly peptide-related impurities, may affect the safety or effectiveness of a peptide drug product. This draft guidance is intended to assist potential applicants in determining when an application for a synthetic peptide drug product that refers to a previously approved peptide drug product of rDNA origin should be submitted as an ANDA rather than an NDA.

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 the submission of ANDAs for certain highly purified synthetic peptide drug products that refer to listed drugs of rDNA origin. 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. This draft guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information required under 21 CFR part 314 for the submission of NDAs and ANDAs is approved under OMB control number 0910–0001, and the submission of controlled correspondence pertaining to ANDAs is approved under OMB control number 0910–0797.

III. Electronic Access

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

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4918]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.