industry; availability

deoxyribonucleic acid; guidance for

listed drugs of recombinant

peptide drug products that refer to
certain highly purified synthetic

abbreviated new drug applications for

[docket no. fda–2017–d–5767]

human services

department of health and

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; guidance for
industrial 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 final
guidance for industry entitled “anda
for certain highly purified synthetic
peptide drug products that refer to
listed drugs of rDNA origin.” this
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
recombinant deoxyribonucleic acid
(rDNA origin should be submitted as an
abbreviated new drug application
(ANDA) under the federal food, drug,
and cosmetic act (FD&C Act) rather
than as a new drug application (NDA)
under the FD&C Act. this guidance
to receive an electronic copy of the
document. please use the document
number 2019–16505 and complete title
to identify the guidance you are
requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no
collection of information, it does refer to
previously approved FDA collections
of information. therefore, clearance by the
Office of Management and Budget
(OMB) under the Paperwork Reduction
Act of 1995 (PRA (44 U.S.C. 3501–
3521) is not required for this guidance.
The previously approved collections of
information are subject to review by
OMB under the PRA. The collections of
information in the following FDA
regulations and guidance have been
approved by OMB as listed in the
following table:

<table>
<thead>
<tr>
<th>21 CFR part; guidance; or FDA form</th>
<th>Topic</th>
<th>OMB control No.</th>
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</thead>
<tbody>
<tr>
<td>807, subpart E</td>
<td>Premarket notification</td>
<td>0910–0120</td>
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<tr>
<td>814, subparts A through E</td>
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<td>Humanitarian Device Exemption</td>
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<td>“De Novo Classification Process (Evaluation of Automatic Class III Designation)”</td>
<td>De Novo classification process</td>
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<td>Q-submissions</td>
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</tr>
<tr>
<td>801 and 809</td>
<td>Medical Device Labeling Regulations</td>
<td>0910–0485</td>
</tr>
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</table>


Lauren K. Roth,
Acting Principal Associate Commissioner for
Policy.

[FR Doc. 2021–10598 Filed 5–19–21; 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; guidance for
industry; availability

agency: food and drug administration, hhs.

action: notice of availability.

summary: the food and drug
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product that refers to a previously
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(rDNA origin should be submitted as an
abbreviated new drug application
(ANDA) under the federal food, drug,
and cosmetic act (FD&C Act) rather
than as a new drug application (NDA)
under the FD&C Act. this guidance
finalizes the draft guidance of the same
title issued on October 3, 2017.

DATES: the announcement of the
guidance is published in the federal
register on May 20, 2021.

ADDRESSES: you may submit either
electronic or written comments on
agency guidances 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 publicly available, 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): docket
management staff (hfa–305), food and
drug administration, 5630 Fishers
Lane, rm. 1061, rockville, MD 20852.

• for written/paper comments
submitted to the docket management
staff, FDA will post your comment, as
well as any attachments, except for
information submitted, marked and
identified, as confidential, if submitted
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

• 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.govinfo.gov/content/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. You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1672, Silver Spring, MD 20993–0002. 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.

505(j) of the FD&C Act (21 U.S.C. 355(j)) rather than as an NDA under section 505(b) of the FD&C Act. This guidance finalizes the draft guidance entitled “ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin” issued on October 3, 2017 (82 FR 46075). FDA considered comments received on the draft guidance as the guidance was finalized. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved 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 guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs or https://www.regulations.gov.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the Federal Register of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidelines by July 19, 2021 to ensure that the Agency considers your comments before it begins work on the final versions of the guidances.

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.