We have made no adjustments to the currently approved burden estimate for the information collection. While we have received comments previously suggesting our burden estimate may be too low, the comments did not discuss the basis for such a conclusion. We therefore specifically invite individual respondent experience with the information collection and associated collection burden.

Based on our experience with the information collection over the past 3 years, we estimate that 55 respondents will submit 1 premarket notification each. We assume that extracting and summarizing relevant information from existing files and presenting it in a format that meets the requirements of §190.6 will take approximately 20 hours of work per notification. We have carefully considered the burden associated with the premarket notification requirement and believe that estimates greater than 20 hours are likely to include burden associated with researching and generating safety data for a new dietary ingredient. We believe that the burden of the premarket notification requirement on industry is minimal and reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance with the FD&C Act. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA’s regulation on new dietary ingredient notifications, §190.6(a), requires the manufacturer or distributor of the dietary supplement or of the new dietary ingredient to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, §190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act.

Dated: March 22, 2018.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1184]

Gastrointestinal Drugs Advisory Committee and the Pediatric 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) announces a forthcoming public advisory committee meeting of the Gastrointestinal Drugs Advisory Committee and the Pediatric Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 3, 2018, from 8 a.m. to 4:30 p.m.

ADDRESS: DoubleTree by Hilton Hotel Bethesda—Washington DC, Grand Ballroom, 8120 Wisconsin Ave., Bethesda, MD 20814–3624. The conference center’s telephone number is 301–652–2000. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.


FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1184. The docket will close on May 2, 2018. Submit either electronic or written comments on this public meeting by May 2, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 2, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of May 2, 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.

Comments received on or before April 19, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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, Room 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–N–1184 for “Gastrointestinal Drugs Advisory Committee; Notice of Meeting: Establishment of a Public
Timely manner (see

Advisory Committee on

confidential information redacted/

on its website prior to the

material available to the public no later

modifications that impact a previously

Docket: Request for Comments.”

Reconsider recommendations

database

2018–06168 Filed 3–27–18; 8:45 am

the Federal Advisory Committee Act (5

the information at:

May be found at

Note: This document contains

in the docket and, except for

addition of the final rule

requests by April 12, 2018.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND

HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1129]

Agency Information Collection

Activities; Proposed Collection;

Comment Request; National

Agriculture and Food Defense Strategy

Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug

Administration (FDA or Agency) is

announcing an opportunity for public

comment on the proposed collection of

certain information by the Agency.

Under the Paperwork Reduction Act of

1995 (PRA), Federal Agencies are

required to publish notice in the

Federal Register concerning each

proposed collection of information and
to allow 60 days for public comment in
response to the notice. This notice

solicits comments on the information

collection requirements for a voluntary

survey for the U.S. Department of

Federal Register about last minute

modifications that impact a previously

announced advisory committee meeting
cannot always be published quickly

enough to provide timely notice.

Therefore, you should always check

the FDA’s website at https://www.fda.gov/

AdvisoryCommittees/default.htm and

scroll down to the appropriate advisory

committee meeting link, or call the

advisory committee information line to

learn about possible modifications

before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss

new drug application (NDA) 209904 for

stannosporin injection, for intramuscular use, submitted by

InfaCare Pharmaceutical Corporation,

proposed for the treatment of neonates
greater than or equal to 35 weeks of

gestational age with indicators of

hemolysis who are at risk of developing

severe hyperbilirubinemia.

FDA intends to make background

material available to the public no later

than 2 business days before the meeting.

If FDA is unable to post the background

material on its website prior to the

meeting, the background material will

be made publicly available at the

location of the advisory committee

meeting, and the background material

will be posted on FDA’s website after

the meeting. Background material is

available at https://www.fda.gov/

AdvisoryCommittees/Calendar/

default.htm. Scroll down to the

appropriate advisory committee meeting

link.

Procedure: Interested persons may

present data, information, or views,
orally or in writing, on issues pending

before the committees. All electronic

and written submissions submitted to

the Docket (see ADDRESSES) on or before

April 19, 2018, will be provided to the

committees. Oral presentations from the

public will be scheduled between

approximately 1:15 p.m. and 2:15 p.m.

Those individuals interested in making

formal oral presentations should notify

the contact person and submit a brief

statement of the general nature of the

evidence or arguments they wish to

present, the names and addresses of

proposed participants, and an

indication of the approximate time

requested to make their presentation on

or before April 11, 2018. Time allotted

for each presentation may be limited. If

the number of registrants requesting to

speak is greater than can be reasonably

accommodated during the scheduled

open public hearing session, FDA may

conduct a lottery to determine the

speakers for the scheduled open public

hearing session. The contact person will

notify interested persons regarding their

request to speak by April 12, 2018.

Persons attending FDA’s advisory

committee meetings are advised that

FDA is not responsible for providing

access to electrical outlets.

For press inquiries, please contact the

Office of Media Affairs at fdao@fda.hhs.gov or 301–796–4540.

FDA welcomes the attendance of the

public at its advisory committee

meetings and will make every effort to

accommodate persons with disabilities.

If you require special accommodations
due to a disability, please contact Jay R.

Fajiculay (see FOR FURTHER INFORMATION

CONTACT) at least 7 days in advance of

the meeting.

FDA is committed to the orderly

conduct of its advisory committee

meetings. Please visit our website at

https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on

public conduct during advisory

committee meetings.

Notice of this meeting is given under

the Federal Advisory Committee Act (5

U.S.C. app. 2).

The committees will discuss

severe hyperbilirubinemia.

Stannosporin injection, for

stannosporin injection, for

allergic reactions, as well as

FDA’s policies and procedures

applicable to the approval of

new drug applications and

biological products.

Any public oral presentations

will be scheduled at approximately 1:15 p.m.

and 2:15 p.m.

The contact person will

The committees will discuss

7 days prior to the meeting.

To the extent feasible, the

FDA is not responsible for

providing

If you do not wish your name and

contact information to be made publicly

available, you can provide this

information to be made publicly

available, you can provide this

information to those submitted as

“confidential” will not be disclosed

after coming to the meeting.

The contact person will

on the call may not speak more than

3 minutes, and the contact person will

notify interested persons regarding their

request to speak by April 12, 2018.

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U.S.C. app. 2).