IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2019

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications and certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2019, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2019 based on the fully supported FTE hourly rates for FY 2019 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

<table>
<thead>
<tr>
<th>Fee category</th>
<th>Estimated fees for FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renewal application fee for recognized accreditation body ......................</td>
<td>$21,350</td>
</tr>
<tr>
<td>Renewal application fee for directly accredited certification body ...........</td>
<td>$28,999</td>
</tr>
<tr>
<td>Annual fee for certification body directly accredited by FDA .................</td>
<td>$21,056</td>
</tr>
</tbody>
</table>

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the invoice date. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: August 24, 2018.

Leslie Kux,
Associate Commissioner for Policy.
SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. Preliminary agenda topics include discussions on strategic realignment of NTP and updates on peer reviews. Please see the preliminary agenda for information about the specific presentations. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting website (http://ntp.niehs.nih.gov/go/165) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting website.

Meeting and Registration: The meeting is open to the public with time scheduled for oral public comments. Registration to view the webcast is by October 9, 2018, at http://ntp.niehs.nih.gov/go/165. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written and oral public comments on the agenda topics. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. The deadline for submission of written comments is October 1, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Oral Public Comments: Registration for oral comments is on or before October 1, 2018, at http://ntp.niehs.nih.gov/go/165. Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. Oral comments may be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one time slot, and five minutes will be allotted to each time slot.

Methods of Diagnosing and Treating CHAPLE, a Newly Identified Orphan Disease Description of Technology

This technology is directed towards a potential treatment for a new disease, CHAPLE (Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy), identified by NIAID researchers. CHAPLE is associated with GI symptoms and vascular thrombosis and is caused by loss-of-function variants in the gene encoding the complement regulatory protein CD55. The disease is caused by enhanced activation of the complement pathway and complement-mediated induction of intestinal lymphangiectasia and protein-losing enteropathy. There is no current therapy for the newly described heritable genetic disorder and the symptoms are poorly controlled. CHAPLE is similar to other complement activating diseases that can be fatal, particularly for patients who develop severe thrombosis. Recent off-label use of a complement inhibiting drug, eculizumab (CD55 inhibitor) was shown to provide a dramatic benefit in patients with CHAPLE disease with an immediate correction of gastrointestinal protein loss. Thus, identification of CD55 deficiency in CHAPLE patients, and the possibility to use complement inhibitory drugs provide opportunities for treatment.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Diagnostic.
- Therapeutic.

Competitive Advantages

- There is no therapy currently approved for CHAPLE disease, and