risks. For example, available quality control materials may contain glucose but do not contain other reducing sugars (*e.g.,* galactose, lactose). Therefore, such materials might not readily detect an issue with the device's safety or effectiveness in detecting other reducing sugars, before causing harm. The petition provided insufficient information to support the position that changes in the device that could affect safety and effectiveness will either be readily detectable or not materially increase risks. Moreover, changes in the device that could affect safety and effectiveness might materially increase the risk of injury, incorrect diagnosis, or ineffective treatment given the device type's intended uses. The petition also did not provide information to the contrary. The petition did not provide any information regarding the fourth factor.

In addition to these four factors, FDA considers the ''limitations on exemption.'' Manufacturers of any commercially distributed device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA prior to marketing the device when any of the limitations of exemption are exceeded. The general limitations of exemption from premarket notification contained in § 862.9 (21 CFR 862.9) are broadly applicable to in vitro diagnostic (IVD) devices classified under part 862 (21 CFR part 862). Under § 862.9, the exemption from the premarket notification requirements applies, in the case of IVD devices, only to those devices under part 862 for which misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA has previously assessed that this limitation is exceeded, and a premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of an IVD device, when such device is intended for use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism (§ 862.9(c)(2)) or intended for use in diabetes management (§ 862.9(c)(5)). The copper reduction tablet test described in the petition is intended for such uses and would likely exceed the limitations just described.

Accordingly, for all of the foregoing reasons, the petition failed to demonstrate that a premarket submission is not necessary to provide a reasonable assurance of the safety and effectiveness of the device intended for such uses. Therefore, FDA is issuing this order denying the petition requesting exemption for a method, metallic reduction, glucose (urinary, nonquantitative) test system in a reagent tablet format that is intended to measure glucosuria (glucose in urine) from the premarket notification requirements. Manufacturers of this device type must continue to submit and receive FDA clearance of a 510(k) before marketing their device, as well as comply with all other applicable requirements under the FD&C Act.

V. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: September 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23901 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 570

[Docket No. FR–5767–N–05]

RIN 2506–AC35

Section 108 Loan Guarantee Program: Announcement of Fee To Cover Credit Subsidy Costs

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Announcement of fee.

SUMMARY: This document announces the fee that HUD will collect from borrowers of loans guaranteed under HUD's Section 108 Loan Guarantee Program (Section 108 Program) to offset the credit subsidy costs of the guaranteed loans pursuant to commitments awarded in FY 2017.

DATES: *Effective Date:* November 3, 2016.

FOR FURTHER INFORMATION CONTACT: Paul Webster, Director, Financial Management Division, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street, SW., Room 7180, Washington, DC 20410; telephone number 202–402–4563 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339. FAX inquiries (but not comments) may be sent to Mr. Webster at 202–708–1798 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113–235, approved December 16, 2014) (2015 Appropriations Act) provided that ''the Secretary shall collect fees from borrowers . . . to result in a credit subsidy cost of zero for guaranteeing'' Section 108 loans. The Continuing Appropriations Act, 2016 (Public Law 114–53, approved September 30, 2015) continued the 2015 provision. This continued funding act was followed by The Consolidated Appropriations Act, 2016, Public Law 114–133, approved December 18, 2015) (2016 Appropriations Act), which had identical language regarding Section 108 credit subsidy to the 2015 Appropriations Act. The fiscal year 2017 HUD appropriations bills under consideration in the House of Representatives (H.R. 5394), and the Senate (S. 2844) also have identical language regarding the credit subsidy for the Section 108 Program, and it is expected that, when enacted, the final fiscal year 2017 appropriations act will as well.

On November 3, 2015, HUD published a final rule (80 FR 67626) following a February 5, 2015 proposed rule (80 FR 6470) that amended the Section 108 Program regulations at 24 CFR part 570 to establish additional procedures, including procedures for determining the amount of the fee and for a 30-day public comment process when HUD adopts changes to the assumptions underlying the fee calculation or if the fee structure itself raises new considerations for borrowers.

HUD is required to collect fees from Section 108 borrowers when necessary to offset the credit subsidy costs to the Federal government to guarantee Section 108 loans. Following

consideration of the public comments submitted in response to HUD's February 5, 2015 proposed rule (80 FR 6469) that proposed the fee required to offset the credit subsidy costs, on November 3, 2015, HUD issued an announcement of fee (80 FR 67634) to set the fee for Section 108 loan disbursements under loan guarantee commitments awarded in FY 2016 at 2.58 percent of the principal amount of the loan.

II. FY 2017 Fee: 2.59 Percent of the Principal Amount of the Loan

This document sets the fee for Section 108 loan disbursements under loan guarantee commitments awarded in FY 2017 at 2.59 percent of the principal amount of the loan. This amount was proposed in the President's FY 2017 budget.[1] HUD will collect this fee from borrowers of loans guaranteed under the Section 108 Program to offset the credit subsidy costs of the guaranteed loans pursuant to commitments awarded in FY 2017, as authorized by the 2017 appropriations act.

For this fee document, HUD is not changing the underlying assumptions or creating new considerations for borrowers. The calculation of the FY 2017 fee uses the same fee calculation model as the FY 2016 announcement of fee, but incorporates updated information regarding the composition of the Section 108 portfolio and the timing of the estimated future cash flows for defaults and recoveries. The calculation of the fee is also affected by the discount rates required to be used by HUD when calculating the present value of the future cash flows as part of the Federal budget process.

As described in 24 CFR 570.712(b), HUD's credit subsidy calculation is based on the amount required to fully offset the credit subsidy cost to the Federal government associated with making a Section 108 loan guarantee. As a result, HUD's credit subsidy cost calculations incorporated assumptions based on: (i) data on default frequency for municipal debt where such debt is comparable to loans in the Section 108 loan portfolio; (ii) data on recovery rates on collateral security for comparable municipal debt; (iii) the expected composition of the Section 108 portfolio by end users of the guaranteed loan funds (*e.g.,* third party borrowers and public entities); and (iv) other factors that HUD determined were relevant to this calculation (*e.g.,* assumptions as to loan disbursement and repayment patterns).

Taking these factors into consideration, HUD determined that the fee for disbursements made under loan guarantee commitments awarded in FY 2017 will be 2.59 percent, which will be applied only at the time of loan disbursements. Note that future documents may provide for a combination of up-front and periodic fees for loan guarantee commitments awarded in future fiscal years but, if so, will provide the public an opportunity to comment if appropriate under 24 CFR 570.712(b)(2).

The expected cost of a Section 108 loan guarantee is difficult to estimate using historical program data because there have been no defaults in the history of the program that required HUD to invoke its full faith and credit guarantee or use the credit subsidy reserved each year for future losses.[2] This is due to a variety of factors, including the availability of Community Development Block Grant (CDBG) funds as security for HUD's guarantee as provided in 24 CFR 570.705(b). As authorized by Section 108 of the Housing and Community Development Act of 1974, as amended (42 U.S.C. 5308), borrowers may make payments on Section 108 loans using CDBG grant funds. Borrowers may also make Section 108 loan payments from other anticipated sources but continue to have CDBG funds available should they encounter shortfalls in the anticipated repayment source. Despite the program's history of no defaults, federal credit budgeting principles require that the availability of CDBG funds to repay the guaranteed loans cannot be assumed in the development of the credit subsidy cost estimate (see 80 FR 67629, November 3, 2015). Thus, the estimate must incorporate the risk that alternative sources are used to repay the guaranteed loan in lieu of CDBG funds, and that those sources may be insufficient. Based on the rate that CDBG funds are used annually for repayment of loan guarantees, HUD's calculation of the credit subsidy cost must take into account the possibility of future defaults if those CDBG funds were not available. The fee of 2.59 percent of the principal amount of the loan will offset the expected cost to the government due to default, financing costs, and other relevant factors. To arrive at this measure, HUD analyzed data on comparable municipal debt over an extended 16 to 23-year period. The estimated rate is based on the default and recovery rates for general purpose municipal debt and industrial development bonds. The cumulative default rates on industrial development bonds (14.62 percent) were higher than the default rates on general purpose municipal debt (0.25 percent) during the period from which the data were taken. (The recovery rates for industrial development bonds and general purpose debt were 74.76 and 90.27 percent, respectively.) These two subsectors of municipal debt were chosen because their purposes and loan terms most closely resemble those of Section 108 guaranteed loans. In this regard, Section 108 guaranteed loans can be broken down into two categories: (1) loans that finance public infrastructure and activities to support subsidized housing (other than financing new construction) and (2) other development projects (*e.g.,* retail, commercial, industrial). The 2.59 percent fee was derived by weighting the default and recovery data for general purpose municipal debt and the data for industrial development bonds according to the expected composition of the Section 108 portfolio by corresponding project type. Based on the dollar amount of Section 108 loan guarantee commitments awarded during the period from FY 2011 through FY 2015, HUD expects that 25 percent of the Section 108 portfolio will be similar to general purpose municipal debt and 75 percent of the portfolio will be similar to industrial development bonds. In setting the fee at 2.59 percent of the principal amount of the guaranteed loan, HUD expects that the amount generated will fully offset the cost to the Federal government associated with making guarantee commitments awarded in FY 2017. Note that the FY 2017 fee represents only a .01 percent increase over the FY 2016 fee of 2.58 percent. This is due primarily to updated loan repayment patterns and discount rates used in calculating the present value of cash flows. These are variable that ordinarily are modified in the credit subsidy calculation.

This document establishes a rate that does not constitute a development decision that affects the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this document is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

[1] The FY 2017 President's Budget for HUD is available at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/hud.pdf.* The fee is specified in table 6 of the Federal Credit Supplement to the 2017 budget and is available at: *https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/cr_supp.pdf*

[2] U.S. Department of Housing and Urban Development, Study of HUD's Section 108 Loan Guarantee Program, (prepared by Econometrica, Inc. and The Urban Institute), September 2012.

Dated: September 28, 2016.

Harriet Tregoning,

Principal Deputy Assistant, Secretary for Community Planning and Development.

[FR Doc. 2016–23986 Filed 10–3–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9786]

RIN 1545–BC70

Credit for Increasing Research Activities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the application of the credit for increasing research activities. These final regulations provide guidance on software that is developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer (internal use software). These final regulations also include examples to illustrate the application of the process of experimentation requirement to software. These final regulations will affect taxpayers engaged in research activities involving software.

DATES: *Effective date:* These regulations are effective on October 4, 2016.

Applicability date: For date of applicability see § 1.41–4(e).

FOR FURTHER INFORMATION CONTACT: Martha Garcia or Jennifer Records of the IRS Office of the Associate Chief Counsel (Passthroughs and Special Industries) at (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations that amend the Income Tax Regulations (26 CFR part 1) relating to the credit for increasing research activities (research credit) under section 41 of the Internal Revenue Code (Code). Section 41(d)(4)(E) provides that, except to the extent provided by regulations, research with respect to software that is developed by (or for the benefit of) the taxpayer primarily for internal use by the taxpayer is excluded from the definition of qualified research under section 41(d). Software that is developed for use in an activity that constitutes qualified research for purposes of section 41(d) and software that is developed for use in a production process with respect to which the general credit eligibility requirements under section 41 are satisfied are internal use software, but are not excluded under section 41(d)(4)(E) from the definition of qualified research and are not subject to these regulations.

On January 20, 2015, the Treasury Department and the IRS published in the **Federal Register** (80 FR 2624, January 20, 2015) a notice of proposed rulemaking (REG–153656–03, 2015–5 IRB 566) under section 41 (the proposed regulations) relating to the research credit. Comments responding to the proposed regulations were received and a public hearing was held on April 17, 2015. After consideration of all of the comments received, these final regulations adopt the proposed regulations as revised by this Treasury decision.

Summary of Comments and Explanation of Provisions

I. Definition of Internal Use Software

The proposed regulations provided that software is developed by (or for the benefit of) the taxpayer primarily for internal use if the software is developed by the taxpayer for use in general and administrative functions that facilitate or support the conduct of the taxpayer's trade or business. General and administrative functions, as defined in the proposed regulations, are limited to (1) financial management functions, (2) human resource management functions, and (3) support services functions. Financial management functions are functions that involve the financial management of the taxpayer and the supporting recordkeeping. Human resource management functions are functions that manage the taxpayer's workforce. Support services functions are functions that support the day-to-day operations of the taxpayer, such as data processing or facilities services.

Commenters expressed concern that the list of general and administrative functions in the proposed regulations was overly broad and included functions that do not represent ''back-office'' functions. In particular, the commenters noted that inventory management, marketing, legal services, and government compliance services can provide significant benefits to third parties and may be developed to enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system. Specifically, one commenter noted that many inventory management software applications are an integral part of a taxpayer's supply chain management system and can be readily seen as part of the modern ''front office.'' This commenter noted that modern inventory management software usually requires interaction with a number of third party vendors to ensure the correct flow of raw materials and a corresponding flow of finished goods. Additionally, the commenter added that inventory management is inherently customer facing because it provides the proper amount of inventory to customers at the point of sale at the right time. Another commenter added that marketing is an external-facing function by nature, and software that supports marketing is necessarily intended to interact with third parties.

The Treasury Department and the IRS understand that many modern software systems perform more than back-office functions. These software systems commonly provide benefits to vendors and include functions that are customer facing. Additionally, software with functions such as marketing or inventory management may not provide solely back-office functions, but may also contain functions that enable a taxpayer to interact with third parties or to allow third parties to initiate functions or review data on the taxpayer's system. Recognizing such situations, the proposed regulations provided rules under § 1.41–4(c)(6)(iv)(C) (dual function rules) to evaluate whether software that has both back-office and front-office functions is developed primarily for internal use. The Treasury Department and the IRS continue to believe that functions such as inventory management, marketing, legal services, and government compliance services provide support to day-to-day operations of a taxpayer in carrying on business regardless of the taxpayer's industry and that the benefits that such functions may provide to third parties are collateral and secondary. In addition, the Treasury Department and the IRS believe the dual function rules in these final regulations sufficiently address these comments by allowing taxpayers to identify subsets of elements of dual function software that only enable a taxpayer to interact with third parties or allow third parties to initiate functions or review data. Accordingly, the list of general and administrative functions provided in the proposed regulations remains unchanged in the final regulations.

Another commenter referred to the tax software example in the preamble to the proposed regulations which notes that tax software developed by a company engaged in providing tax services to its customers is not used by the taxpayer in general and administrative functions