Supplementary Information:

I. Introduction

The Federal Deposit Insurance Corporation (FDIC) is proposing supervisory guidance to clarify the FDIC’s application of principles of safe and sound banking practices and consumer protection in connection with deposit advance products. This proposed guidance describes the principles that the FDIC expects FDIC-supervised financial institutions to follow in connection with any deposit advance product to address potential reputational, compliance, legal and credit risks. The FDIC expects institutions to apply the principles set forth in this guidance to any deposit advance product they offer.

II. Description of Guidance

A deposit advance product is a small-dollar, short-term loan that a depository institution (bank) makes available to a customer whose deposit account reflects recurring direct deposits. The customer is allowed to take out a loan, which is to be repaid from the proceeds of the next direct deposit. These loans typically have high fees, are repaid in a lump sum in advance of the customer’s other bills, and often do not utilize fundamental and prudent banking practices to determine the customer’s ability to repay the loan and meet other necessary financial obligations.

The FDIC continues to encourage banks to respond to customers’ small-dollar credit needs; however, banks should be aware that deposit advance products can pose a variety of safety and soundness, compliance, consumer protection, and other risks. The FDIC is proposing guidance to ensure that any bank offering these products does so in a safe and sound manner and does not engage in practices that would increase credit, compliance, legal, and reputation risks to the institution.

III. Guidance

The text of the proposed Supervisory guidance on deposit advance products follows:

FDIC Proposed Guidance on Deposit Advance Products

The Federal Deposit Insurance Corporation (FDIC) is proposing supervisory guidance to depository institutions (banks) that offer deposit advance products. This guidance is intended to ensure that banks are aware of the significant risks associated with deposit advance products. The guidance
also supplements the FDIC’s existing guidance on payday loans and subprime lending. Although the FDIC encourages banks to respond to customers’ small-dollar credit needs in a responsible manner and with reasonable terms and conditions, deposit advance products pose a variety of safety and soundness, compliance, and consumer protection risks to banks.

Background. A deposit advance product is a type of small-dollar, short-term credit product offered to customers maintaining a deposit account, reloadable prepaid card, or similar deposit-related vehicle at a bank. The bank provides a credit feature that allows the customer to take out a loan in advance of the customer’s next direct deposit. The advance is based on the customer’s history of recurring deposits. Typically, the advance is offered as an open-end line of credit. While the specific details of deposit advance products vary from bank to bank, and also may vary over time, those currently offered incorporate some or all of the characteristics described below.

Cost. The cost of the deposit advance is typically based on a fee structure, rather than an interest rate. Generally advances are made in fixed dollar increments and a flat fee is assessed for each advance. For example, a customer may obtain advances in increments of $20 with a fee of $10 per every $100 advanced. The cost of the deposit advance can be more expensive than other forms of credit, such as a credit card, or a traditional line of credit.

Eligibility, Loan Limits and Ability To Repay. Typically, a customer is eligible for a deposit advance if the deposit account has been open for a certain period of time and the customer receives recurring deposits. Banks typically require a minimum sum to be directly deposited each month for a certain period of time in order for the borrower to be eligible for a deposit advance loan. Currently, some banks permit a recurring deposit as low as $100.

The maximum dollar amount of the advance is typically limited to a percent or amount of the recurring monthly deposit. For example, some banks permit the deposit advance to be the lesser of $500 or 50 percent of the scheduled direct deposits from the preceding statement cycle, rounded up to the nearest $10. The advance limit does not include the fee associated with the advance. In addition, some banks will allow the advance even if the customer’s account is currently overdrawn. Some banks also permit a customer to exceed the advance limit, at the bank’s discretion.

Typically, the bank does not analyze the customer’s ability to repay the loan based on recurring debits or other indications of a need for residual income to pay other bills. The decision to advance credit to borrowers, based solely on the amount and frequency of their deposits, stands in contrast to banks’ traditional underwriting standards for other products, which typically include an assessment of the borrower’s ability to repay the loan based on an analysis of the borrower’s finances.

Repayment. Repayment is generally required through an electronic payment of the fee and the advance with the next direct deposit. Typically, the bank is paid first before any other transactions are paid. In some cases, a bank will apply a time limit on how soon it will take the fee and the advance from the direct deposit, but the time limit is minimal, usually one or two days. If the first deposit is insufficient to repay the fee and the advance, the repayment will be obtained from subsequent deposits. If the deposits are insufficient to repay the fee and the advance within a certain time period, typically 35 days, then the bank executes a forced repayment by sweeping the underlying deposit account for the remaining balance. Unlike a payday lender, the bank has automatic access to the underlying deposit account. In some cases, borrowers may be able to access program features that allow for a longer repayment period than 35 days; however, this is not usually allowed.

If the deposit account funds are insufficient to repay the fee and the advance, then the account goes into overdraft status. Some banks will charge an overdraft fee based on the deposit advance overdrawing the account. Other banks will only charge overdraft fees based on any subsequent transactions that overdraw the account.

Although the deposit advance limit is based on an amount or percentage of the monthly deposit, the repayment can be based on a shorter time period. For example, if a customer receives direct deposits of $500 every other Friday from her employer, her monthly direct deposit would be $1000. Under the typical bank’s advance limit, she could receive an advance of $500 with a fee of $50. If she obtains the deposit advance on the Thursday before her payday, then the bank will obtain repayment on Friday. The bank will take the entire $500 paycheck. In addition, the customer will still owe $50 in principal because the deposit was only sufficient to pay the $50 fee and $450 in principal. Assuming the customer has no other source of income, the customer will need to rely on savings to pay bills until the next paycheck. At the next paycheck, the bank will take the remaining $50 in principal and the customer will have $450 to pay all outstanding bills.

Some banks have implemented alternative repayment methods that provide more flexibility to the customer. For example, some banks will permit repayment to extend through to the second direct deposit if the first direct deposit falls below a specific dollar threshold. In addition, some banks allow payment by mail rather than electronic transfer, but may charge a fee for this option. Finally, some banks offer an installment loan option, but may also charge an additional fee or may only offer this option if the customer cannot repay the advance and fee from the monthly deposits.

Repeat Usage Controls. Banks often have repeat usage limits that trigger a "cooling off" period during which the customer cannot take out a deposit advance, or the credit limit is reduced. For example, some banks may prevent an advance for 35 days if the borrower has used the service at least once each month in the previous six-month period. However, the customer can resume use of the product after the 35-day period is completed. Other banks may prevent an advance for one full billing cycle if the customer borrows the entire amount of the advance each month in the previous six months. However, the customer can avoid this limit by taking out something less than the maximum advance.

Marketing and Access. Banks market deposit advance products as intended to assist customers through a financial emergency or to meet short term needs. These advances, however, are typically not included with the bank’s list of available credit products, but are instead listed as a deposit account feature. Customers are alerted to the availability of the products by a reference on their account statement or a “button” or hot link on their personal account Web page, but it is not clear
that the customer is made equally aware of less expensive alternatives.

Supervisory Concerns of Deposit Advance Loans

Although the FDIC encourages banks to respond to customers’ small-dollar credit needs, deposit advance products pose supervisory risks. These products share a number of characteristics seen in traditional payday loans, including: high fees; very short, lump-sum repayment terms; and inadequate attention to the consumer’s ability to repay. As such, banks need to be aware of these products’ potential to harm consumers, as well as elevated safety and soundness, compliance, and consumer protection risks.

The combined impact of an expensive credit product coupled with short repayment periods increases the risk that borrowers could be caught in a cycle of high-cost borrowing over an extended period of time. Specifically, deposit advance customers may repeatedly take out loans because they are unable to fully repay the balance in one pay period while also meeting typical recurring and other necessary expenses (e.g., housing, food, and transportation). Customers may feel compelled to take out another loan very soon thereafter to make up for the shortfall. This cycle is referred to as the “churning” of loans and is similar to the practice of “loan flipping” that the OCC, the FDIC and the Board, have previously noted to be an element of predatory lending.3 Though deposit advance products are often marketed as intended for emergency financial assistance, and as unsuitable for meeting a borrower’s recurring or long term obligations, the FDIC believes the product’s design results in consumer behavior that is frequently inconsistent with this marketing and is detrimental to the customer.

To address concerns that certain borrowers become dependent on deposit advance products to meet their daily expenses (as evidenced by their repeated borrowings), certain lenders now require borrowers who have taken out a specified number of deposit advance loans within a certain time frame to wait for a specified period before they are eligible to take out a new loan. However, the FDIC is concerned these “cooling-off” periods can be easily avoided and are ineffective in preventing repeated usage of these high-cost, short-term loans.

Weak underwriting increases the risk that the borrower’s account may become overdrawn and result in multiple overdraft fees when subsequent transactions are presented for payment. Some banks assess overdraft fees when the automatic repayment of the deposit advance loan causes the associated account to reflect a negative balance.

Safety and Soundness Risk

Credit Risk: Borrowers who obtain deposit advance loans may have cash flow difficulties or blemished or insufficient credit histories that limit other borrowing options. The high aggregate cost of numerous and repeated extensions of credit that may be a consequence of this product further increase credit risk. Lenders that offer deposit advance loans typically focus on the amount of the borrower’s monthly deposit for underwriting purposes. Failure to consider whether the income sources are adequate to repay the debt while covering typical living expenses, other debt payments, and the borrower's credit history presents safety and soundness risks.

Numerous and repeated extensions of credit to the same individual may be substantially similar to continuous advances and subject the bank to increased credit risk. While re-aging, extensions, deferrals, renewals, and rewrites of lending products can be used to help borrowers overcome temporary financial difficulties, repeated re-aging credit practices can cloud the true performance and delinquency status of the portfolio.4

Relying on the amount of the customer’s incoming deposits without consideration of expected outflows does not allow for a proper assessment of the customer’s ability to repay the loan and other necessary expenses. This failure to properly assess the borrower’s financial capacity, a basic underwriting principle, increases default risk.

Reputation Risk: Reputation risk is the risk arising from negative public opinion. Deposit advance products are receiving significant levels of negative news coverage and public scrutiny. This increased scrutiny includes reports of high fees and borrowers taking out multiple advances to cover prior advances and everyday expenses. Engaging in practices that are perceived to be unfair or detrimental to the customer can cause a bank to lose community support and business.

Legal Risk: The significant risks associated with deposit advance lending products may subject institutions to the risk of litigation—both from private lawsuits and regulatory enforcement actions.

Third-Party Risk: Banks remain responsible and liable for compliance with all applicable laws and regulations, even for the activities of a third party.5 The FDIC is aware of banks working with third parties to develop, design and service the deposit advance product. The existence of third-party arrangements may, when not properly managed, significantly increase institutions’ legal, operational and reputation risks. Some of the risks are associated with the underlying activity itself, similar to the risks faced by a bank directly conducting the activity. Other potential risks arise from or are heightened by the involvement of a third party, particularly if the third party will receive a portion of the fees. Consequently, third-party arrangements may expose the bank to regulatory action and affect the institution’s ability to establish new or service existing customer relationships.

Compliance and Consumer Protection Related Concerns

Deposit advance products must comply with all applicable federal laws and regulations, some of which are outlined below. State laws also may be applicable, including usury laws and laws on unfair or deceptive acts or practices. It is important that banks have their deposit advance products reviewed by counsel for compliance with all applicable laws prior to implementation. Furthermore, although the guidance below outlines federal laws and regulations as of the date this guidance is published, applicable laws and regulations are subject to amendment. In addition, statutes and regulations will have different applications depending on how a deposit advance product is structured. Banks offering deposit advances should carefully consider whether and how these laws and rules will apply to the particular version of a deposit advance product they are providing. Accordingly, banks should monitor applicable laws and regulations for revisions and to ensure that their deposit advance product is fully compliant. Federal laws and regulations applicable to deposit advance products include, but are not limited to, the following:

3 Subprime Lending Guidance jointly signed by the OCC, the Board, the FDIC and the OTS (January 31, 2001).

4 See the Federal Financial Institutions Examination Council Uniform Retail Credit Classification and Account Management Policy, Federal Register Vol. 65, No. 113, June 12, 2000. This policy is addressed more fully in the “Credit Quality” section.

The Federal Trade Commission Act (FTC Act): Section 5 of the FTC Act prohibits unfair or deceptive acts or practices (UDAP). The FDIC enforces this section pursuant to its authority in Section 8 of the Federal Deposit Insurance Act, 12 U.S.C. 1818. An act or practice is unfair where it: (1) Causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or to competition. Public policy may also be considered. An act or practice is deceptive if: (1) There is a representation, omission, or practice that misleads or is likely to mislead a consumer; (2) the consumer’s interpretation is reasonable under the circumstances; and (3) the misleading representation, omission, or practice is material.

Deposit advance products may raise issues under the FTC Act depending upon how the products are marketed and implemented. Any FTC Act analysis will be dependent on the facts and circumstances in a particular matter.

The prohibition on UDAP applies not only to the product, but to every stage and activity, from product development to the creation and rollout of marketing campaigns, and to servicing and collections. For example, marketing materials and disclosures should be clear, conspicuous, accurate and timely; and should fairly and adequately describe the terms, benefits, potential risks and material limitations of the product.

Truth in Lending Act (TILA): TILA and Regulation Z require creditors to provide cost disclosures for extensions of consumer credit. Different rules apply to Regulation Z disclosures depending on whether the loan is an open- or closed-end credit product. Banks should ensure the product’s disclosures comply with the applicable requirements. TILA advertising rules for open-end credit require that, if an advertisement states any periodic rate that may be applied, it must state the rate as an Annual Percentage Rate, using that term. Similarly, TILA advertising rules for closed-end credit require that, if an advertisement states a rate of finance charge, it must state the rate as an Annual Percentage Rate, using that term.

Electronic Fund Transfer Act (EFTA): A program that involves the use of electronic fund transfers must meet the applicable disclosure and other requirements of EFTA and Regulation E. EFTA requires disclosures, prohibits creditors from mandating that loans be repaid by “preauthorized electronic fund transfers,” and allows borrowers to withdraw authorization for “preauthorized fund transfers.”

Truth in Savings Act (TISA): A program that involves a consumer’s deposit account must meet the disclosure requirements of TISA and Regulation DD. Under TISA, deposit account disclosures must include the amount of any fee that may be imposed in connection with the account and the conditions under which the fee may be imposed. TISA also prohibits institutions from making any advertisement, announcement, or solicitation relating to a deposit account that is inaccurate or misleading or that misrepresents their deposit contracts.

Truth in Savings Act (TISA) disclosures enable consumers to make informed decisions about their deposit accounts at depository institutions. A consumer is entitled to receive TISA disclosures at account opening, when the terms of the consumer’s account are changed, and when a periodic statement is sent.

Equal Credit Opportunity Act (ECOA): Under ECOA and Regulation B, creditors are prohibited from discriminating against an applicant on a prohibited basis in any aspect of a credit transaction. This prohibition applies to deposit advance products. The creditor’s discretion, for example in the application of eligibility requirements, loss mitigation options and fee waivers, may raise fair lending risk. Steering or targeting certain customers on a prohibited basis toward deposit advance products while offering other customers more favorable credit products may also raise fair lending risk. Additionally, providing different product terms or conditions and different servicing or loss mitigation options to similarly situated customers on a prohibited basis may also violate ECOA.

In addition to the general prohibition against discrimination, ECOA and Regulation B contain specific rules concerning procedures and notices for credit denials and other adverse actions. Regulation B defines the term “adverse action,” and generally requires a creditor who takes an adverse action to send a notice to the consumer providing, among other things, the reasons for the adverse action.

Supervisory Expectations

Deposit advance lending presents significant consumer protection and safety and soundness concerns, irrespective of whether the products are issued by a bank directly or by third parties. The FDIC will take appropriate supervisory action to prevent harm to consumers, to address any unsafe or unsound banking practices associated with these products, and to ensure compliance with all applicable laws. Examinations will focus on compliance with applicable consumer protection statutes and potential safety and soundness issues.

Examiners will assess credit quality, including underwriting and credit administration policies and practices. In addition, examiners will assess the adequacy of capital, reliance on fee income, and adequacy of the allowance for loan and lease losses. Compliance with applicable federal consumer protection statutes, management’s oversight, and relationships with third-parties will also be assessed.

Credit Quality: The Uniform Retail Credit Classification and Account Management Policy (Retail Classification Policy) establishes guidelines for classifying consumer loans, such as deposit advance loans, based on delinquency, but also grants examiners the discretion to classify individual retail loans that exhibit signs of credit weakness, regardless of delinquency status. An examiner also may classify consumer portfolios, or segments thereof, where underwriting standards are weak and present unreasonable credit risk.

Deposit advance loans often have weaknesses that may jeopardize the liquidation of the debt. Borrowers often have limited repayment capacity. Banks should adequately review repayment capacity to assess whether borrowers will be able to repay the loan without

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6 15 U.S.C. §§ 45(a) and (n).
7 Joint Board and FDIC guidance on “Unfair or Deceptive Acts or Practices by State-Chartered Banks” (March 11, 2004).
9 See 12 CFR 1026.16(b)(1).
10 See 12 CFR 1026.24(c).
12 See, e.g., 12 CFR 1005.7, 1005.8, and 1005.9.
13 See 12 CFR 1005.10(e).
14 See 12 CFR 1005.10(c).
15 12 U.S.C. 4301 et seq. TISA is implemented by Regulation DD at 12 CFR § 1030 for banks and federal savings associations.
16 See 12 CFR 1030.4(b)(4).
17 See 12 CFR 1030.8.
18 15 U.S.C. 1691 et seq. ECOA is implemented by Regulation B, 12 CFR Part 1002. ECOA prohibits discrimination on the basis of race, color, religion, national origin, sex, marital status, age (provided the applicant has the capacity to contract), the fact that all or part of the applicant’s income derives from a public assistance program, and the fact that the applicant has in good faith exercised any right under the Consumer Credit Protection Act.
20 See 12 CFR §§ 1002.2(c) and 1002.9.
needing to incur further deposit advance borrowing.

Deposit advance loans that have been accessed repeatedly or for extended periods of time are evidence of "churning" and inadequate underwriting. Banks should monitor for repeated or extended use, as will be discussed in greater detail in the discussion of underwriting expectations below.

Underwriting and Credit Administration Policies and Practices: As part of the credit quality review, examiners will assess underwriting and administration policies and practices for deposit advance loan products. Eligibility and underwriting criteria for deposit advance loans, consistent with eligibility and underwriting criteria for other bank loans, should be well documented in the bank’s policy. The criteria should be designed to assure that the extension of credit can be repaid according to its terms while allowing the borrower to continue to meet typical recurring and other necessary expenses such as food, housing, transportation and healthcare, as well as other outstanding debt obligations. Additionally, criteria should ensure that borrowers can meet these requirements without needing to borrow repeatedly. Institutions should maintain appropriate criteria to prevent churning and prolonged use of these products. Underwriting for deposit advance products should occur prior to opening such accounts and should be monitored on an on-going basis. Repetitive deposit advance borrowings indicate weak underwriting and will be criticized in the Report of Examination and then taken into account in an institution’s rating.

Bank policies regarding the underwriting of deposit advance loan products should be written and approved by the bank’s board of directors, and consistent with the bank’s general underwriting standards and risk appetite. Factors a bank should address in its written underwriting policies for deposit advance products include, but are not necessarily limited to, the following:

- **The Length of a Customer’s Deposit Relationship With the Bank.** Banks should ensure that the customer relationship is of sufficient duration to provide the bank with adequate information regarding the customer’s recurring deposits and expenses in order to prudently underwrite deposit advance loans. The FDIC will consider sufficient evidence to be a customer’s deposit advance eligibility to be no less than six months.

- **Classified Credits.** Customers with any delinquent or adversely classified credits should be ineligible.

- **Financial Capacity.** In addition to any eligibility requirements, the bank should conduct an analysis of the customer’s financial capacity including income levels. Underwriting assessments should consider the customer’s ability to repay a loan without needing to borrow repeatedly from any source, including re-borrowing, to meet necessary expenses. The financial capacity assessment should include:
  - An analysis of the customer’s account for recurring deposits (inflows) and checks/credit/customer withdrawals (outflows) over at least six consecutive months. Lines of credit of any sort, including overdrafts, and drafts from savings should not be considered inflows. In reviewing customers’ transactions to determine deposit advance eligibility, the bank should consider the customers’ net surplus or deficit at the end of each of the preceding six months, and not rely on a six-month transaction average.
  - After conducting the above described analysis, determine whether an installment repayment is more appropriate.

- **Cooling Off Period.** Each deposit advance loan should be repaid in full before the extension of a subsequent deposit advance loan, and banks should not offer more than one loan per monthly statement cycle.21 A cooling off period of at least one monthly statement cycle after the repayment of a deposit advance loan should be completed before another advance may be extended in order to avoid repeated use of the short-term product.

- **Increasing Deposit Advance Credit Limits.** The amount of credit available to a borrower should not be increased without a full underwriting reassessment in compliance with the bank’s underwriting policies and in accordance with the factors discussed in this guidance. Additionally, any increase in the credit limit should not be automatic and should be initiated by a request from the borrower.

- **Ongoing Customer Eligibility.** As part of their underwriting for this product, banks should, no less than every six months, reevaluate the customer’s eligibility and capacity for this product. Additionally, banks should identify risks that could negatively affect a customer’s eligibility to receive additional deposit advances. For example:
  - Repeated overdrafts (establish/set a certain number during a specified number of months).
  - Evidence that the borrower is overextended with respect to total credit obligations.

- **Capital Adequacy:** Higher capital requirements generally apply to loan portfolios that exhibit higher risk characteristics and are subject to less stringent loan underwriting requirements. Loans exhibiting subprime credit characteristics are higher risk loans and may require higher levels of capital.

- **Over-Reliance on Fee Income:** Fees associated with deposit advance products should be based on safe and sound banking principles. Institutions should monitor for any undue reliance on the fees generated by such products for their revenue and earnings.

- **Adequacy of the Allowance for Loan and Lease Losses (ALLL):** Examiners will assess whether the ALLL is adequate to absorb estimated credit losses within the deposit advance loan portfolio. Examiners will also determine whether banks engaged in deposit advance lending have methodologies and analyses in place that demonstrate and document that the level of the ALLL is appropriate.

- **Consumer Compliance:** Banks should implement effective compliance management systems, processes and procedures to appropriately mitigate risks. Examiners will review a bank’s program with respect to deposit advance products for compliance with applicable consumer protection statutes and regulations, including TILA, EFTA, TISA, ECOA, and Section 5 of the FTC Act.

- **Management Oversight:** Examiners will assess bank management’s ability to administer a deposit advance loan program and board oversight of the program. Furthermore, examiners will determine whether bank management has established controls and implemented a rigorous analytical process to identify, measure, monitor, and manage the risks associated with deposit advance loans. The bank’s
compliance management system should ensure continuing compliance with applicable federal and state laws, rules and regulations, as well as internal policies and procedures.

Banks should maintain adequate oversight of deposit advance programs and adequate quality control over those products and services to minimize exposure to potential significant financial loss, reputation damage, and supervisory action. Management should provide the appropriate oversight and allocate sufficient qualified staff to monitor deposit advance programs. Results of oversight activities should be reported periodically to the financial institution’s board of directors or designated committee, including identified weaknesses, which should be documented and promptly addressed.

Third-Party Relationships: Because third-party relationships are important in assessing a bank’s overall risk profile, the FDIC’s primary supervisory concern in reviewing a bank’s relationships with third parties is whether the bank is assuming more risk than it can identify, monitor, and manage. Management should allocate sufficient qualified staff to monitor for significant third-party relationships, excessive usage by borrowers, and excessive risk taking by the bank. Therefore, examiners will review the risks associated with all material third-party relationships and activities together with other bank risks. In certain high risk situations, examiners may conduct on-site third-party reviews under specific authorities granted to the FDIC.

Responsible Products To Meet Small-Dollar Credit Needs

The FDIC recognizes the need for responsible small-dollar credit products among consumers. A number of banks are currently offering reasonably priced small-dollar loans at reasonable terms to their customers. The FDIC’s 2007 Affordable Small-Dollar Loan Guidelines (Guidelines) encourage insured institutions to offer small-dollar loan products that have affordable, reasonable interest rates with no or low fees and payments that reduce the principal balance of the loan. The Guidelines indicate that if structured properly, small-dollar loans can provide a safe and affordable means for borrowers to transition away from reliance on high-cost debt products. The FDIC conducted a two-year case study from 2007 to 2009 that demonstrated that safe and affordable small-dollar lending is feasible for banks and resulted in a template of important elements for such lending. The FDIC encourages banks to continue to offer these products, consistent with safety and soundness and other supervisory considerations, and encourages other banks to consider offering such products as well. Properly managed small-dollar loan products offered with reasonable terms and at a reasonable cost do not pose the same level of supervisory risk as deposit advance products.

Dated at Washington, DC, this 25th day of April, 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination and Declaration Regarding Emergency Use of in Vitro Diagnostics for Detection of the Avian Influenza A (H7N9) Virus

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act, 21 U.S.C. 360bbb–3(b)(4). On April 19, 2013, the Secretary determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the avian influenza A (H7N9) virus.

On the basis of this determination, she also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A (H7N9) virus pursuant to section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb–3(b)(1), subject to the terms of any authorization issued under that section. The Secretary also specified that this declaration is a declaration of an emergency with respect to in vitro diagnostics as defined under the Public Readiness and Emergency Preparedness (PREP) Act Declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices signed by then Secretary Michael Leavitt on December 17, 2008. DATES: The determination and declaration are effective April 19, 2013. FOR FURTHER INFORMATION CONTACT: Nicole Lurie, M.D., M.S.P.H., Assistant