The subject of this PIA is which of the following?

- Minor Application (child)

Identify the Enterprise Performance Lifecycle Phase of the system.

- Implementation

Is this a FISMA-Reportable system?

- No

Does the system include a Website or online application available to and for the use of the general public?

- Yes

Identify the operator.

- Agency

Is this a new or existing system?

- New

Does the system have Security Authorization (SA)?

- No

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

The FDA Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The Act puts in place specific restrictions on marketing tobacco products to children and gives FDA authority to take further action in the future to protect public health. To ensure that regulated industry complies with the age and photo identification requirements of the FSPTCA, CTP created the Age Calculator application (Age Calculator or “the app”) for mobile devices. The Age Calculator is intended to assist tobacco retailers in verifying that tobacco product purchasers are at least 18 years old by means of photo identification displaying the bearer’s date of birth. The Age Calculator app is an optional tool for retailers; FDA does not require they use the app to calculate the age of tobacco purchasers.
Describe the type of information the system will collect, maintain (store), or share.

The Age Calculator is intended to assist tobacco retailers in verifying that customers are 18 years old or older by means of photo identification containing the bearer’s date of birth. Tobacco retailers download the app and use it as a tool to verify consumer’s date of birth at the time of purchase. The only type of information the Age Calculator collects and processes is the consumer’s date of birth. That information is maintained only for a fraction of seconds during processing and is not stored anywhere in the app itself, on the mobile device, or on any FDA server. The application does not collect any information about the tobacco retailers using their mobile device. The Age Calculator requires access to the camera of the mobile device. The application does not connect to or access any other application or content of the user’s device. Tobacco retailers are not required to use the Age Calculator. The application is a tool they may freely download from their app store. No registration is required and no data is sent back to CTP as part of the downloading or subsequent use of the application.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

The FDA Age Calculator has features that include: (1) The ability to scan IDs or manually enter the customer’s date of birth to perform a check against the minimum buyer age; (2) On-screen guidelines to aid in centering the ID barcode; (3) “About Us” content with Retailer Overview of FDA Regulations for Selling Tobacco Products; (4) The ability to manage accessibility settings; and (5) In-app Help content.

The application collects consumers’ date of birth to calculate their age only, it is neither stored in the local device nor submitted to any servers. No other information contained is collected, whether from the buyer ID or any other source.

Anyone can download the Age Calculator from the Apple Store or Google Play Store. There are two ways in which the mobile application collects the user’s date of birth. The application performs the age calculation when the retailer scans ID card content or by calculating it using date of birth manually entered in the app by the retailer at the time of purchase. The application is not connected to any database and does not transmit (send) any information collected from the ID card. No information processed by the app is stored in the using retailer’s mobile phone (device).

Retailers have two options using the mobile application to validate the consumer’s age: by selecting “Scan ID” or by selecting “Calculate Manually.”

To use the “Scan ID” option, the user opens the app, from the Home screen clicks on the “Scan ID” button to begin scanning the barcode on any U.S. government, or U.S. territory photo ID (e.g., driver’s license), holds the camera still to scan the barcode on the back of the photo ID. If scanned successfully, the app will extract date of birth from barcode, then calculate the age and display the result with a green pass image (18 or older) or a red “X” do not sell image (buyer is not 18 or older).

To use the “Calculate Manually” option (e.g., if the photo ID does not have a barcode), the user selects “Calculate Manually” at the home screen after opening the app and then manually enters the date of birth displayed on the buyer’s ID.

Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Date of Birth
Indicate the categories of individuals about whom PII is collected, maintained or shared.
  Public Citizens
  “Public Citizens” refers to consumers purchasing the tobacco product.

How many individuals' PII is in the system?
<100

For what primary purpose is the PII used?
The PII is processed is to verify that consumers are at least 18 years and authorized to purchase the tobacco product.

Describe the secondary uses for which the PII will be used.
None.

Identify legal authorities governing information use and disclosure specific to the system and program.
21 U.S.C. 301 et seq., Sec. 102, of the Food, Drug, and Cosmetic Act.

Are records on the system retrieved by one or more PII data elements?
No

Identify the sources of PII in the system.
Directly from an individual about whom the information pertains
In-Person
Hardcopy

Non-Governmental Sources
Public

Identify the OMB information collection approval number and expiration date
Not Applicable.

Is the PII shared with other organizations?
No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.
The mobile application is a tool made available to tobacco retailers for their use to verify and validate consumer’s age (date of birth). Prior to using the application, users consent to the notice displayed on the mobile application stating that the “application accesses the user’s device camera to scan customer IDs. It does not access any other application, program or service on the user’s device. The only personally identifiable information the application processes is customer date of birth used to calculate their age. This information is not transmitted or shared and it is not saved in the user’s device, nor a third party or government server.”
Users consent to the notice by clicking “I Understand.” Additionally, the notice is permanently available under the application's section “About Us.” The FDA does not collect or maintain any information processed by the application. Consumers freely provide their ID to tobacco retailers as a legal requirement under the FSPTCA to demonstrate they are at least 18 years old at the time of the purchase.

Is the submission of PII by individuals voluntary or mandatory?
Voluntary

Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.
Individuals have the option to decline to provide their date of birth and not pursue the purchase of age-restricted tobacco products.
Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

If FDA practices change with regard to the use of the application, the agency will employ appropriate notice and consent procedures. This may include notices and disclaimers when tobacco retailers download the Age Calculator and through an update of this Privacy Impact Assessment.

Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.

Individuals may raise concerns regarding retailer use of their information directly with the retailer. Individuals may also contact FDA for assistance using email, phone and mailing information provided on FDA.gov.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

Not applicable. PII is not maintained.

Identify who will have access to the PII in the system and the reason why they require access.

Others:

The FDA does not collect or maintain any information processed by the application.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Not applicable. The FDA does not collect or maintain any information processed by the application, and developers performing upgrades of the application do not have access to any PII because the app itself does not store any.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Not applicable. The FDA does not collect or maintain any information processed by the application.

Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.

All developers of the application must complete security and privacy awareness training at least once each year.

Describe training system users receive (above and beyond general security and privacy awareness training).

None.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes.

Describe the process and guidelines in place with regard to the retention and destruction of PII.

Not applicable. The FDA does not collect or maintain any information processed by the application.

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

While FDA does not collect any PII through the application, it has implemented several administrative, technical, and physical controls. Administrative safeguards include developer’s training; system documentation that advises on proper use; implementation of non-ability to store PII (neither in the application, nor in the mobile device).

Technical safeguards include role-based access settings to the back-end of the application, firewalls and others. Physical controls include that all system servers used for the update of the application are located at FDA facilities protected by guards, locked facility doors, and climate controls.
Other appropriate controls have been selected from the National Institute of Standards and Technology’s (NIST’s) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

**Identify the publicly-available URL:**
No URL is available. It is only a mobile application.
Note: web address is a hyperlink.

**Does the website have a posted privacy notice?**
Yes

**Is the privacy policy available in a machine-readable format?**
Yes

**Does the website use web measurement and customization technology?**
No

**Does the website have any information or pages directed at children under the age of thirteen?**
No

**Does the website contain links to non-federal government websites external to HHS?**
No

**Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?**
nul