that are available to FDA at the time the classification determination is made.

FDA regularly receives questions from medical product sponsors concerning the classification of their products. We believe that efficient, effective regulation would be facilitated by providing guidance on this topic. This guidance discusses the request for designation (RFD) process for obtaining a formal determination of a product's classification, and provides general concepts regarding FDA's decision process for making classification determinations. While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, issues most frequently arise regarding whether a product should be classified as either a drug or a device. Accordingly, this guidance focuses particularly on cases in which a product may be classified as a drug or device.

This guidance is organized into two substantive sections. Section II provides information on the RFD process for obtaining a formal determination of whether a product is classified as a drug or device and on obtaining other feedback from FDA on product classification questions. Section III discusses general concepts and definitions relating to FDA's decisional process for making classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.

FDA carefully considered the comments received on the two draft guidances in preparing this final guidance. We have combined the two documents into one and made other changes for clarity and ease of reference. For example, we have revised the discussion of the Agency's interpretation and application of the term ''chemical action'' in the definition of device at section 201(h) of the FD&C Act, to more clearly explain the Agency's approach. With regard to this issue and others, we have also included additional examples to illustrate the application of the Agency's current thinking.

In light of comments received, we have also reconsidered inclusion of content on the status of prior Agency classification determinations. FDA has had limited experience with reevaluating classification determinations as the issue rarely arises for FDA to consider. In addition, it can raise a variety of complex scientific and regulatory questions. Accordingly, we have concluded that it is not appropriate to address the topic further in guidance at this time. We will continue to address the issue on a case-by-case, fact-specific basis as needed, in a transparent manner as permitted by, and consistent with, applicable legal requirements. Any stakeholder who has questions regarding the classification of a currently marketed product or whether that classification should be relied upon with respect to a proposed product is encouraged to contact the Office of Combination Products.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 3 have been approved under OMB control number 0910–0523.

IV. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm.*

Dated: September 21, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20522 Filed 9–25–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5319]

Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on a potential approach for device sponsors who seek to obtain marketing authorization for their products that are labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use.

DATES: The public hearing will be held on November 16, 2017, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by October 26, 2017. Sections II and III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until January 15, 2018. Late, untimely filed comments will not be considered.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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, Rm. 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–2017–N–5319 for ''Devices Referencing Drugs; Public Hearing; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Associate Director for Policy, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20933, 301–796–8930, *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Medical products are often intended and labeled for use in conjunction with other medical products marketed by different sponsors (as used in this document, ''sponsor'' includes an applicant or manufacturer). In some cases, the medical products are of different types (such as drug and device, biological product and device, or drug and biological product). Typically, the different sponsors collaborate when the two products are to be used together for a new intended use. In some cases, products intended for use with one another comprise a ''combination product'' as the term is defined in 21 CFR 3.2(e). Regardless of whether the products meet the definition of a combination product, collaboration between the sponsors can facilitate product development and obtaining marketing authorization for the products for the combined use, and can, thereby, enable access to innovative treatment options for patients. Inclusion of the combined use in the labeling of both products helps ensure user understanding, and the collaboration can also be important to ensuring the ongoing safety and effectiveness of the products for the combined use.

Sometimes, however, sponsors seek marketing authorization from FDA for a medical product for a new use with the approved, marketed medical product of another sponsor (*i.e.,* not included in the labeling for the approved, marketed product), and the sponsor of the approved, marketed product does not wish to pursue the new use or work with the other product sponsor. Generally, such proposed products have been devices proposing new uses with approved, marketed drugs (referred to in this notice as devices referencing drugs or DRDs), though other scenarios have been proposed as well, such as drugs proposed for new uses with cleared or approved, marketed devices. This notice focuses on DRDs.

In FDA's experience, DRDs may be proposed: (1) To enhance the safety or effectiveness of the marketed drug for its already approved indication; (2) for use with the approved drug for an indication for which the drug is not approved; or (3) to provide some other benefit, such as increasing user comfort or convenience. Such new uses have generally also involved a change in how the drug is used or administered, such as a change in dose, route, or rate of administration.

FDA seeks to ensure that safe and effective medical products can be brought onto the market in a timely manner. The Agency encourages development of products that advance public health, particularly those that significantly improve the safety or effectiveness of an existing treatment or that address an unmet medical need. DRDs have the potential to advance the public health by offering new uses with approved, marketed drugs that might not otherwise be developed, because the drug sponsor does not wish to pursue the new use. At the same time, DRDs raise unique public health, scientific, regulatory, and legal issues.

FDA, in cooperation with the Drug Information Association, held a public meeting in 2005 on combined uses of separately distributed products.[1] That meeting focused on the public health, legal, regulatory, and scientific issues[2] that arise when sponsors seek to develop or market a product of one type (device, drug, or biological product) that would be labeled for use with an approved product of a different type, where the proposed use is not included in the labeling for the approved product.

As reflected in the notice for that meeting and the presentations and discussions at the meeting, devices intended for a new combined use with a drug raise unique public health, scientific, regulatory and legal issues when the sponsors for the two products do not work together on the new combined use of the two products. Since that time, FDA has gained greater experience with these issues and believes that many of these issues for DRDs could be addressed under the approach described below.

FDA wishes to obtain further public input through a more focused hearing

[1] Links to the **Federal Register** notice for the workshop, presentations given, and a full transcript of the proceedings are available at: *https://www.fda.gov/combinationproducts/meetingsconferencesworkshops/ucm116623.htm.*

[2] Although the issues discussed at the meeting were described as public health or legal issues, they also included scientific and regulatory issues.

on the Agency's potential approach for premarket review of proposed DRDs. The Agency is seeking this type of public engagement because of the potential importance of the issue for the public health and the need for input across the medical product industry and among public health stakeholders regarding how FDA should proceed.

II. Purpose and Scope of the Public Hearing

The purpose of the public hearing is to obtain comment from stakeholders on the potential approach described below, for premarket review of DRDs. As described above, DRDs, for purposes of this document and hearing, are devices that are intended for a use with an approved, marketed drug that is not in the labeling for the approved drug, where the drug application is held by a different sponsor that does not wish to pursue or collaborate on the new use with the device sponsor. The approach described below might be appropriate, for example, for drug delivery systems seeking to be labeled for use with an approved drug, for an indication for which that drug has not been approved (*e.g.,* to administer the drug to treat a different disease or condition or a new patient population). We also welcome comment on any public health, scientific, regulatory, or legal considerations relating to DRDs and other medical products seeking to be labeled for new uses with approved, marketed medical products of a different type where the sponsor for the approved, marketed product does not wish to pursue or collaborate on the new use. The comments that FDA receives from this public hearing may help inform the further development of this approach.

A. A Potential Approach for Premarket Review of DRDs

FDA strongly recommends collaboration between sponsors on new combined uses of their medical products. The Agency is prepared to work with sponsors to facilitate such collaboration. When sponsors work together, they usually have an ongoing relationship that enables them to resolve many of the public health, scientific, regulatory, and legal issues that may arise as a result of two products being the responsibility of two independent sponsors. Such collaboration also can provide important information to support a regulatory decision (see below). Where collaboration between sponsors is not feasible, for example, because one sponsor does not wish to collaborate, FDA believes that the following factors could help address many of the public health, scientific, regulatory, and legal issues associated with DRDs. In doing so, these factors could allow for a DRD to be reviewed and approved via a device premarket authorization pathway [3] without approval of conforming labeling changes for the approved, marketed drug through a new drug application (NDA) or supplement to an NDA (see Section II.B *Submission Considerations* for further discussion).

B. Factors

DRD sponsors should be able to address the following issues as discussed below:

1. Safety and Effectiveness of the New Use of the Drug. The DRD sponsor is able to demonstrate the safety and effectiveness of the new use of the drug that is included in the DRD labeling, by providing substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use described in the proposed DRD labeling and showing that the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed DRD labeling, as this is the standard that applies to new uses of drugs (see 21 U.S.C. 355(c) and (d)). If there are multiple approved versions of the approved drug product(s) referenced in the DRD labeling (including generic versions), the DRD sponsor is able to demonstrate the generalizability of the new use with all such versions of the drug product.

2. User Confusion and Medication Error/Use Error. Given the potential for user confusion or medication error/use error, for example, due to certain differences in the labeling for the DRD and the approved drug that it is referencing, the DRD sponsor is able to demonstrate that the potential for user confusion or error has been adequately addressed. The DRD labeling must provide adequate directions for the new use with the approved, marketed drug.

3. Postmarket Change Management. The DRD sponsor is able to demonstrate that it is able to address safety or effectiveness issues associated with changes to the approved, marketed drug, for example, by demonstrating: That the likelihood of changes to the approved, marketed drug is low; changes to the drug are unlikely to raise safety or effectiveness issues with respect to the conditions of use with the drug as described in the DRD labeling; and periodic testing will be conducted and be adequate to assure ongoing safety and effectiveness of the combined use. It is important that these issues be addressed because the DRD sponsor does not have a relationship with the sponsor for the approved, marketed drug, and, therefore, any changes to the two products will not be coordinated or communicated in advance.

4. Postmarket Safety. The DRD sponsor is able to demonstrate that it has a postmarket safety plan to adequately address adverse events, including medication errors, related to the drug when used with the DRD. It is important that its postmarket safety plan allows the DRD sponsor to adequately capture, report, and respond appropriately to adverse events associated with the new drug use described in the DRD labeling, because the DRD sponsor does not have a relationship with the sponsor(s) of the approved, marketed drug and because the DRD sponsor will often be uniquely positioned to understand and address adverse events resulting from the new use of the drug described in the DRD labeling.

5. Data Reliance. The DRD sponsor is able to provide all information needed to evaluate the safety and effectiveness of the new use with the approved drug referenced in the DRD labeling, without relying on any proprietary information for the approved drug (*e.g.,* by instead relying on non-product-specific published literature, generalizable knowledge). The DRD sponsor may also be able to include in its application safety and effectiveness data and information from the marketing application for the drug that are publicly available, for example, if the approved reference listed drug has been withdrawn from sale, provided that FDA has determined that the approved reference listed drug was not withdrawn from sale for reasons of safety or effectiveness (see 21 U.S.C. 355(*l*) and 21 CFR 314.161 and 314.430). Generally, a DRD sponsor would not have a right of reference to proprietary information on the approved drug with which the DRD is proposed to be used because the DRD sponsor has no relationship with the sponsor of the approved drug.

C. Submission Considerations

At the investigational stage, depending on the details of the investigational plan, a DRD sponsor may seek to submit an investigational new drug application (IND) or an investigational device exemption application (IDE). Either way, the Center for Drug Evaluation and Research

[3] FDA has not determined at this time whether DRDs may be reviewed through other device premarket authorization pathways besides premarket approval applications (PMAs), but FDA intends to consider this issue and welcomes comment on it.

(CDER) and the Center for Devices and Radiological Health (CDRH) would collaborate on the review. DRD sponsors should consult with CDER and CDRH as to which application to submit for a particular investigation.

FDA believes that a PMA would generally be the appropriate device marketing application because, *e.g.,* DRDs are expected to represent a new intended use or raise different questions of safety or effectiveness as compared to a legally marketed predicate device. Generally, PMAs for DRDs would be reviewed by CDRH, and CDRH would collaborate with CDER on the review of the DRD. CDRH would have the lead on device-specific issues, and CDER would have the lead on drug-specific issues. The Centers would identify any review aspects where review considerations overlap, to ensure Agency alignment on how to address these considerations and communicate about them to DRD sponsors.

D. Questions for Commenters To Address

FDA welcomes all feedback on the potential approach and on any public health, scientific, regulatory, and legal issues raised by it. We seek public comment on the factors and submission considerations described in this notice, and propose the following questions in an effort to prompt substantive input from stakeholders:

1. Are there public health, scientific, regulatory, or legal issues that should be considered with respect to this potential approach for DRDs? If so, are there ways to address those issues?

2. Is each of the factors and submission considerations described above appropriate? If not, why not? What modifications would you propose and why? Are there additional factors or submission considerations that the Agency should take into account? Please provide examples to illustrate your view.

3. Should the approach described in this notice be limited to certain situations, such as where the combined use would potentially address an unmet medical need for a serious or life-threatening condition? If so, please provide a detailed analysis in support of your view, including its legal justification.

4. With respect to the user confusion and medication error/use error factor, are there other issues that DRD sponsors should address or that FDA should consider, to ensure that the DRD labeling provides adequate directions for the new use with the approved, marketed drug, without approval of conforming labeling changes for the approved, marketed drug? What issues should be considered with respect to promotional activities by the DRD sponsor and/or by any sponsors for the drug being referenced?

5. With regard to the postmarket change management factor, what would be examples of circumstances in which the DRD sponsor would be able to adequately address this factor? What types of postmarket changes to the drug should the DRD sponsor be prepared to identify and address? What postmarket mechanisms, including specific testing or monitoring, would be appropriate to ensure ongoing safety and effectiveness of the combined use?

6. When multiple versions of the drug, including generics, are marketed, what challenges exist in identifying which versions of the drug can be used with the DRD? How can DRD sponsors make this information clear to health care providers, pharmacists, and patients?

7. What challenges exist at the investigational application stage, and how can those challenges be addressed? Are there circumstances where an IND would be the more appropriate investigational application for a clinical investigation of a DRD? Are there circumstances where an IDE would be the more appropriate investigational application?

8. How may this approach impact future product development?

9. Would an approach similar to the potential approach presented in this notice be appropriate for other types of combined uses (*e.g.,* drugs referencing devices where the device sponsor does not wish to collaborate on the new use)? If so, how should the factors, submission considerations, or both be modified for other types of combined uses? Are there additional factors that should be considered for other types of combined uses?

10. Are there other possible approaches that may be used to seek marketing authorization for combined uses of drugs and devices where product sponsors are unable or unwilling to collaborate? Please provide a detailed analysis in support of your proposed approach, including its legal justification.

11. Recognizing that collaboration is preferable, what actions can FDA and stakeholders take to encourage and facilitate collaboration between device sponsors and sponsors of approved, marketed drugs to develop new combined uses of their medical products?

12. Would an approach similar to the potential approach presented in this notice be appropriate in the case where a drug sponsor would like to include in the drug labeling the use of one or more approved or cleared companion diagnostics for its new drug in the same class as the drugs for which the companion diagnostic is approved or cleared but none of the companion diagnostic sponsors intend to add the new drug to the device labeling? If so, how should the factors, submission considerations, or both be modified? Are there additional factors that should be considered? Are there other possible approaches that may be used for such circumstance? Please provide a detailed analysis in support of your proposed approach, including its legal justification.

III. Registration

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by webcast (see *Streaming Webcast of the Public Hearing*)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm572528.htm* by October 26, 2017 and provide complete contact information for each attendee (*i.e.,* name, title, affiliation, address, email address, and telephone number). Those without email access can register by contacting John Barlow Weiner by October 26, 2017 (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to *combination@fda.gov* on or before November 2, 2017. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An

agenda for the hearing and any other background materials will be made available 5 days before the hearing at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm572528.htm.*

If you need special accommodations because of a disability, please contact the Office of Combination Products at 301–796–8930 or *combination@fda.gov* at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live webcast of the hearing. To join the hearing via the webcast, please go to *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm572528.htm.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *https://www.fda.gov.*

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: September 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20521 Filed 9–25–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

COMPETES Reauthorization Act Challenge Competition

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB) announces a prize competition to support the development and testing of low-cost, scalable technology-based innovations to meet the needs of families and health care providers of children with special health care needs (CSHCN), particularly children with medical complexity (CMC), to improve the quality of care, patient empowerment, and family experiences while saving costs to the health care system.

FOR FURTHER INFORMATION CONTACT: James Resnick, Office of the Associate Administrator, MCHB, *JResnick@hrsa.gov,* (301) 443–3222, or Marie Mann, Division of Services for Children with Special Health Needs, MCHB, *MMann@hrsa.gov,* (301) 443–4925.

SUPPLEMENTARY INFORMATION: On January 4, 2011, the America COMPETES Reauthorization Act of 2010 was signed into law allowing the use of challenges and prize competitions increasing agencies' ability to promote and harness innovation. Competitions run by the federal government result in a number of benefits to the public, including the following:

(a) Increasing the number and diversity of the individuals, teams, and organizations that are addressing a particular problem or challenge of national significance;

(b) Improving the skills of the participants in the competition; and

(c) Directing attention to new market opportunities and stimulating private sector investment.

This challenge structured in three phases, reach a diverse population of innovators and solvers, including coders, public health experts, individuals affiliated with academic institutions, research and development communities in the private sector, and others. All submissions will be evaluated and separate prizes will be awarded for each of the three phases below.

Phase 1: Design
Phase 2: Development and Small Scale Testing
Phase 3: Scaling

Estimated dates for each phase are as follows:

Phase 1: Effective on January 22, 2018
Phase 1 Submission Period Ends: April 20, 2018, 11:59 p.m. ET
Phase 1 Judging Period: April 21–May 18, 2018
Phase 1 Winners Announced: May 25, 2018
Phase 2 Begins: May 29, 2018
Phase 2 Submission Period Ends: October 26, 2018
Phase 2 Judging Period: October 29–November 20, 2018
Phase 2 Winners Announced: December 4, 2018
Phase 3 Begins: December 7, 2018
Phase 3 Submission Period Ends: May 10, 2019
Phase 3 Winner Announced: May 30, 2019

Subject of Challenge Competition

MCHB is sponsoring the Making Technology Work for Care Planning and Coordination for Children with Special Health Care Needs Challenge. CSHCN, particularly CMC, often rely on multiple systems, services, and health professionals to maintain health and optimize well-being. Care coordination and care planning centered on the comprehensive needs of the child and family can lead to improved quality and experience of care, as well as more cost-effective care. Even with the presence of care coordinators and the development of shared care plans, communication and collaboration gaps remain because care coordinators and the shared care plans often are specific to providers and/or systems. Families have expressed frustration about working with the multiple systems and the lack of communication and coordination between them. They try to address the gap by assuming responsibility for their children's 24/7 care and care coordination. However, they often encounter numerous obstacles and barriers to fulfilling this role, including difficulty obtaining needed information or guidance from health professionals. They desire resources like electronic and informational tools to allow easy aggregation of information and sharing