Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) The FDA does not follow the NIH Page Limitation Guidelines or the Enhanced Peer Review Scoring Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Peer Review Process.
Components of Participating Organizations	Center of Drug Evaluation and Research/Office of Pharmaceutical Science/Office of Generic Drugs (CDER)
Funding Opportunity Title	**Effect of Physicochemical Properties of Ophthalmic Formulations on Ocular Bioavailability (U01)**
Activity Code	U01 Research Project – Cooperative Agreements
Announcement Type	New
Related Notices	• May 25, 2012 - See Notice NOT-FD-12-013. Notice of Change in Section I. Funding Opportunity Description, Detailed Description. • May 4, 2012 - See Notice NOT-FD-12-008. Notice of Correction to Expiration Date, Funds Available and Award Budget. • May 4, 2012 - See Notice NOT-FD-12-005. Notice of Correction of Application Due Date.
Funding Opportunity Announcement (FOA) Number	**RFA-FD-12-020**
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.103
Funding Opportunity Purpose	The purpose of this project is to study the effect of various physicochemical properties of ophthalmic suspensions and emulsions on ocular bioavailability. Formulations having the same active and inactive ingredients in the same concentrations may still exhibit differences in physicochemical properties due to differences in the manufacturing process. Key physicochemical properties which impact clearance, distribution, and drug release will be investigated. The following physicochemical properties should be investigated in the project study: Globule/particle size distribution Surface charge Osmolality pH Viscosity Dispersibility Suitable bioequivalence methods are lacking for many generic ophthalmic

	formulations. Suspensions and emulsions are commonly employed as ophthalmic vehicles as they can easily be applied topically to the eye. The results from this project will help to understand the relationship between physicochemical properties and their impact on ocular bioavailability, and will also be used to help determine bioequivalence study recommendations for generic ophthalmic suspensions and emulsions.

Key Dates

Posted Date	April 27, 2012
Open Date (Earliest Submission Date)	May 1, 2012
Letter of Intent Due Date	Not Applicable.
Application Due Date(s)	(New Date **June 22, 2012** per NOT-FD-12-005), Original Date May 31, 2012, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not Applicable.
Scientific Merit Review	June, 2012
Advisory Council Review	August, 2012
Earliest Start Date(s)	September, 2012
Expiration Date	(Extended to **June 23, 2012** per NOT-FD-12-008), Original Date June 1, 2012
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

Ophthalmic drugs are commonly formulated as topical eye drops for the treatment of anterior ocular disorders. While water-soluble drugs can be administered topically as an aqueous solution, water-insoluble drugs (such as steroids) typically require administration as a suspension or as an emulsion. Ophthalmic steroids are widely used to suppress inflammation in the anterior eye for a wide range of indications including conjunctivitis, dry eye, and inflammation from surgical trauma.

Generic drug products must demonstrate pharmaceutical equivalence and bioequivalence to the reference listed drug (RLD) to gain FDA approval. Pharmaceutical equivalence requires that the drug product contains the same active ingredient(s) as the RLD, be identical in strength, dosage form, and route of administration, and that it meets compendial or other applicable standards of strength, quality, purity, and identity. Bioequivalence requires an absence of a significant difference in the rate and extent to which the active ingredient in pharmaceutically equivalent products becomes available at the site of action.

For generic ophthalmic solutions that are qualitatively (Q1) and quantitatively (Q2) the same as the RLD, bioequivalence is considered to be self-evident and a waiver of in vivo study requirements may be requested. For other ophthalmic dosage forms that are Q1 and Q2 the same as the RLD, bioequivalence must be demonstrated as manufacturing differences have the potential to affect ocular bioavailability.

Manufacturing differences may result in physicochemical differences which in turn may affect clearance, distribution, and release of the drug. Suitable bioequivalence methods are lacking for many generic ophthalmic formulations, including suspensions and emulsions. An investigation of the relationship between various physicochemical properties and their effect on ocular bioavailability will help FDA establish guidelines for the determination of bioequivalence of ophthalmic suspensions and emulsions.

Objectives

This project will investigate the relationship between various physicochemical properties and ocular bioavailability of an ophthalmic steroid formulated as an emulsion or suspension which is Q1 and Q2 the same as the RLD. To assess the effect of various physicochemical properties on ocular bioavailability, in vitro and in vivo studies (in animals) should be conducted.

Detailed Description

The following physicochemical properties should be investigated in the project study:

Globule/particle size distribution
Surface charge
Osmolality
pH
Viscosity
Dispersibility

The project will involve two stages:

1. In vitro study – Formulations with different physicochemical properties are manufactured using a selected steroid and characterized in vitro. Drug release and stability tests are conducted to understand how differences in physicochemical properties may affect ocular bioavailability. Formulations with key physicochemical properties which demonstrate the greatest potential impact on ocular bioavailability are selected for testing in vivo.

2. In vivo study – Formulations selected based on the results of the in vitro study are tested in an animal model. A pharmacokinetic study should be conducted by assessing the ocular distribution of the steroid in various eye tissues and organs at various time points. A clinical endpoint study may be conducted as an alternative or to supplement the results of the pharmacokinetic study.

Section II. Award Information

Funding Instrument	Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities.
Application Types Allowed	New The OER Glossary and the SF 424 (R&R) Application Guide provide details on these

	application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications received. FDA/CDER intends to commit up to $400,000 in FY 2012. It is anticipated that one (1) award will be made, not to exceed $400,000 in total costs (direct plus indirect).
Award Budget	The amount of financial assistance requested from FDA may not exceed $400,000.
Award Project Period	1 year

FDA grants policies as described in the HHS Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for FDA support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the HHS Grants Policy Statement, **are** allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- Central Contractor Registration (CCR) – must maintain an active registration, to be renewed at least annually
- Grants.gov
- eRA Commons

All Program Directors/Principal Investigators (PD(s)/PI(s)) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least 4-6 weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for FDA support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

FDA will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. FDA will not accept any application that is essentially the same as one already reviewed.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

Page Limitations

All page limitations described in the SF424 Application Guide and must be followed, with the following exceptions or additional requirements:

- For this specific FOA, the Research Strategy section is limited to 20 pages.

PHS 398 Research Plan Component

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix

Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Foreign Institutions

Foreign (non-US) institutions must follow policies described in the HHS Grants Policy Statement, and procedures for foreign institutions described throughout the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov, the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, FDA's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the FDA Grants Policy Statement.

Pre-award costs are allowable only as described in the HHS Grants Policy Statement.

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders:
All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to FDA.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the FDA Grants Office and responsiveness by components of participating organizations, FDA. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-10-115.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the FDA mission, all applications submitted to the FDA in support of biomedical and behavioral research are evaluated for scientific and technical merit through the FDA objective review system.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project

is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the Human Subjects Protection and Inclusion Guidelines.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for

Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genome Wide Association Studies (GWAS).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Group(s), in accordance with FDA's Objective Review Policy and Procedures, using the stated review criteria.

As part of the objective review process, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Appeals of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned to the appropriate FDA Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Cancer Advisory Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by objective review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Information regarding the disposition of applications is available in the HHS Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, FDA will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements as noted in the HHS Grants Policy Statement.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and FDA grant administration policies. The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the FDA purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the FDA as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and FDA policies.

FDA staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

Participate in developing a study protocol;

Participate in data analysis;

Review method validation;

Review and conduct quality assurance of results;

Participate in writing manuscripts for publication;

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

Areas of Joint Responsibility include:

None; all responsibilities are divided between awardees and FDA staff as described above.

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement for additional information on this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding FDA grant resources)
Telephone 301-435-0714
TTY 301-451-5936
Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov

Scientific/Research Contact(s)

Stephanie Kim
Food and Drug Administration /Center of Drug Evaluation and Research/Office of Pharmaceutical Science/Office of Generic Drugs
Telephone: 240-276-9308
Email: Stephanie.Kim@fda.hhs.gov

Peer Review Contact(s)

Lisa Ko
Food and Drug Administration/Office of the Commissioner/Office of Acquisitions and Grants Services
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Email: Lisa.Ko@fda.hhs.gov

Stephanie Kim
Food and Drug Administration /Center of Drug Evaluation and Research/Office of Pharmaceutical Science/Office of Generic Drugs
Telephone: 240-276-9308
Email: Stephanie.Kim@fda.hhs.gov

Financial/Grants Management Contact(s)

Lisa Ko
Food and Drug Administration/Office of the Commissioner/Office of Acquisitions and Grants Services
Telephone: 301-827-5095
Email: Lisa.Ko@fda.hhs.gov

Section VIII. Other Information

Recently issued trans-FDA policy notices may affect your application submission. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Office of Extramural Research (OER)
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland
20892
Department of Health and Human Services (HHS)
USA.gov Government Made Easy

NIH . . . *Turning Discovery Into Health*

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.