

Navigating Peptide Drug Regulation: Comparative Insights from FDA and CDSCO Frameworks

Praveen R.B^{1*}, Prof. Dr. C. Vijaya Raghavan²

^{1*}Student, Kerala University of Health Sciences, Medical College P.O., Thrissur, Kerala, India, PIN 680596

²Principal & Professor, Department of Pharmaceutics, Chemists College of Pharmaceutical Sciences and Research, Ernakulam, Kerala, India, PIN 682308

Corresponding Author: Praveen R. B.*

Email: praveenbalakrishnan.rb@gmail.com, Contact No: +919360356510

Abstract

Peptide therapeutics have emerged as an important class of pharmaceutical products because of their high biological specificity, potent pharmacological activity and broad therapeutic applications. Peptide-based medicines are used or investigated for the management of metabolic, endocrine, cardiovascular, oncological and other diseases. Despite their therapeutic advantages, peptide drug development presents several regulatory challenges related to molecular characterization, impurities, manufacturing consistency, stability, pharmacokinetics, formulation, immunogenicity and clinical evaluation.¹ The regulatory pathway for peptide therapeutics differs among jurisdictions because regulatory authorities apply different statutory frameworks, terminology, submission procedures and scientific requirements. This research article comparatively examines the regulatory frameworks governing peptide therapeutics in the United States and India, with particular emphasis on the U.S. Food and Drug Administration (FDA) and the Central Drugs Standard Control Organisation (CDSCO). The study uses a descriptive, comparative and analytical methodology based predominantly on secondary data, including regulatory guidelines, statutory provisions, official regulatory documents and scientific literature. The research evaluates regulatory requirements associated with preclinical development, clinical trials, chemistry, manufacturing and controls (CMC), marketing authorization and post-marketing surveillance. The analysis indicates that both the FDA and CDSCO employ structured regulatory systems based on the fundamental principles of quality, safety and efficacy. In the United States, development of a novel peptide drug generally involves an Investigational New Drug (IND) application followed by clinical development and submission of a New Drug Application (NDA), where applicable. FDA has also issued peptide-specific clinical pharmacology recommendations addressing hepatic impairment, drug-drug interactions, QTc prolongation and immunogenicity.^{2,3} In India, investigational new drugs and clinical trials are regulated principally under the New Drugs and Clinical Trials Rules, 2019 (NDCTR 2019), with CDSCO responsible for regulatory review of relevant applications.^{4,5} The comparison demonstrates substantial similarity in the overall regulatory objectives of the two systems but also identifies differences in regulatory terminology, approval pathways, submission procedures and product-specific scientific guidance. Increasing regulatory convergence, scientifically justified product characterization, early regulatory consultation and internationally compatible technical standards may facilitate efficient development and global access to peptide therapeutics.

Keywords: *Peptide therapeutics; peptide drugs; FDA; CDSCO; regulatory affairs; IND; NDA; NDCTR 2019; clinical trials; CMC; pharmaceutical regulation.*

How to cite this article: Praveen R.B^{1*} Prof. Dr. C. Vijaya Raghavan². Navigating Peptide Drug Regulation: Comparative Insights from FDA and CDSCO Frameworks. Int J Drug Deliv Technol. 2026;16(85s):340-346. DOI: 10.25258/ijddt.16.85s.30.

1. Introduction

1.1 Background

Peptide therapeutics are biologically active molecules composed of amino acids and occupy an important position in modern pharmaceutical development. Their ability to interact selectively with biological receptors and other molecular targets has enabled their application in several therapeutic areas. The uploaded study describes peptide therapeutics in relation to their molecular characteristics, therapeutic applications, advantages and limitations and identifies regulatory evaluation as an important aspect of their development.¹

Compared with many conventional small-molecule drugs, peptides can demonstrate high target selectivity and biological potency. These characteristics may reduce activity at unintended targets and can provide useful therapeutic effects in diseases where receptor-mediated or hormone-like mechanisms are involved.

However, peptides can also have limitations such as susceptibility to enzymatic degradation, physicochemical instability, formulation challenges and, depending on the molecule and route, poor oral bioavailability.¹

The development of peptide therapeutics therefore requires simultaneous consideration of pharmaceutical quality, nonclinical safety, clinical pharmacology, clinical efficacy and manufacturing consistency. Regulatory authorities must determine whether the proposed product has been sufficiently characterized and whether the manufacturing process consistently produces a product with the intended quality attributes. An important regulatory challenge is that the characterization of a peptide product may extend beyond establishing its nominal amino-acid sequence. Manufacturing-related impurities, degradation products, aggregates or other variants can potentially influence the

quality and performance of the final product. FDA regulatory-science programs have specifically investigated analytical approaches for characterization of impurities in peptide products.⁶

1.2 Importance of Regulatory Evaluation of Peptide Therapeutics

Drug regulation exists to ensure that medicinal products reaching patients meet appropriate standards of quality, safety and efficacy. For peptide therapeutics, these principles are particularly important because the product's characteristics can depend strongly on the manufacturing process and analytical controls.

The quality assessment of a peptide may involve:

- identity
- amino-acid sequence
- purity
- related substances
- process-related impurities
- degradation products
- potency
- biological activity
- stability
- manufacturing consistency
- container-closure systems

The regulatory evaluation must therefore connect pharmaceutical development with clinical performance. FDA's peptide-specific draft guidance illustrates this point. The guidance discusses clinical pharmacology considerations including hepatic impairment, drug-drug interactions, QTc prolongation and immunogenicity and explains that these factors can influence pharmacokinetics, safety and efficacy.³

1.3 Regulatory Significance of the United States and India

The United States represents one of the major pharmaceutical markets and has a highly developed regulatory framework administered by FDA. For new drugs, the development process generally involves an IND during clinical investigation and a marketing application such as an NDA when the sponsor seeks approval.^{2,7}

India has also established a structured framework for new-drug development and clinical trials. The New Drugs and Clinical Trials Rules, 2019 were notified under the Drugs and Cosmetics Act, 1940 and provide specific regulatory provisions concerning new drugs, clinical trials and related activities.⁴

CDSCO's Investigational New Drug Division states that an IND application is required for permission to conduct clinical trials and for the import or manufacture of an investigational new drug, with applications processed through the SUGAM portal under the NDCTR framework.⁵

The source study therefore identifies the comparison of FDA and CDSCO regulatory requirements as an important research area, particularly in relation to clinical trials, documentation, approval pathways, regulatory challenges and market access.¹

2. Aim

To comparatively evaluate the regulatory requirements and approval pathways for peptide therapeutics in the United States and India, with particular emphasis on FDA and CDSCO regulatory frameworks.

3. Objectives

1. To describe peptide therapeutics and their major therapeutic applications.
2. To examine the regulatory framework governing peptide therapeutics in the United States.
3. To evaluate the regulatory framework governing peptide therapeutics in India.
4. To compare the clinical-trial pathways followed under FDA and CDSCO.
5. To compare major quality, CMC and documentation requirements.
6. To identify similarities and differences between the two regulatory systems.
7. To identify regulatory challenges associated with peptide-drug development.
8. To examine the potential impact of regulatory differences on development and market access.
9. To identify opportunities for regulatory harmonization.

These objectives are consistent with the objectives specified in the uploaded source document.¹

4. Methodology

4.1 Study Design

A descriptive, comparative and analytical research design was adopted. The study does not involve experimental laboratory work or clinical experimentation. Instead, it analyzes regulatory requirements and approval pathways using secondary information. The methodology follows the approach outlined in the uploaded research document, which identifies comparative analysis, regulatory documents and scientific literature as the principal sources of information.¹

4.2 Sources of Data

Primary regulatory sources included:

- FDA guidance documents
- FDA regulatory information
- U.S. federal drug regulations
- CDSCO regulatory documents
- New Drugs and Clinical Trials Rules, 2019
- CDSCO information on investigational new drugs
- CDSCO information on new-drug approvals

Secondary sources included scientific literature, pharmaceutical regulatory literature, published reviews, regulatory-science publications and the uploaded research document.

4.3 Comparative Parameters

10. Regulatory authority
11. Definition/classification of investigational products
12. Preclinical requirements
13. Clinical-trial authorization
14. Clinical-development stages
15. CMC requirements

16. Quality and analytical characterization
17. Marketing authorization
18. Ethics oversight
19. Post-marketing surveillance
20. Generic/abbreviated development pathways
21. Peptide-specific regulatory considerations

5. Results

5.1 General Regulatory Characteristics of Peptide Therapeutics

The analysis shows that peptide therapeutics require evaluation across several interconnected dimensions.

5.1.1 Molecular characterization

A peptide product must be appropriately characterized to establish its identity and quality. Depending on the product, analytical characterization may include determination of molecular mass, sequence, purity, related substances and other relevant characteristics.

5.1.2 Impurity characterization

Impurities can originate from synthesis, purification, processing or degradation. Their identification and control are therefore important elements of pharmaceutical development. FDA has conducted regulatory-science research specifically addressing complex peptide impurity mixtures and analytical methods for peptide products.⁶

5.1.3 Stability

Peptide molecules can be sensitive to environmental and formulation conditions. Stability studies are therefore important for determining appropriate storage conditions, shelf life and specifications.

5.1.4 Pharmacokinetics

Pharmacokinetic evaluation determines how the body absorbs, distributes, metabolizes and eliminates the peptide. Route of administration is particularly important for peptides because many peptide molecules are susceptible to degradation and may have limited systemic exposure when administered through certain routes.

5.1.5 Immunogenicity

Immunogenicity is another consideration in peptide development. FDA's peptide clinical pharmacology guidance specifically identifies immunogenicity risk as a consideration in peptide drug development.³

6. FDA Regulatory Framework for Peptide Therapeutics

6.1 FDA Regulatory Pathway

The general development pathway for a new peptide drug product can be represented as:

Discovery and development → nonclinical studies → IND → Phase I → Phase II → Phase III → NDA → FDA review → approval → post-marketing surveillance

This sequence represents the general pathway and does not mean that every peptide product follows exactly the same development program. FDA identifies the IND as the regulatory mechanism used to authorize investigation of an investigational drug in humans.²

6.2 Investigational New Drug Application

The IND represents a critical stage in U.S. drug development.

An IND submission generally includes information relating to:

- investigational product
- manufacturing and controls
- pharmacology and toxicology
- previous human experience where applicable
- clinical protocols
- investigator information
- safety monitoring

The purpose of the IND framework is to provide FDA with sufficient information to evaluate whether proposed clinical investigation can proceed under appropriate conditions.²

For peptide therapeutics, the quality section is particularly important because the clinical material must be adequately characterized and manufactured under appropriate controls.

6.3 Clinical Development in the United States

Phase I

Phase I studies generally focus on initial human safety, tolerability, pharmacokinetics and dose-related information. For peptide products, clinical pharmacology may be especially relevant because exposure can be influenced by route of administration, metabolism and formulation.

Phase II

Phase II studies generally investigate preliminary efficacy and dose-response relationships in patients. Dose selection is particularly important for peptides because pharmacodynamic responses may not always correlate simply with plasma concentrations.

Phase III

Phase III studies provide confirmatory evidence of efficacy and safety in larger patient populations and support the proposed indication and labeling. The exact clinical-development program depends on the characteristics of the product and the disease being treated.

6.4 Peptide-Specific Clinical Pharmacology

FDA issued the draft guidance Clinical Pharmacology Considerations for Peptide Drug Products in December 2023. The guidance defines a peptide, for the purpose of that guidance, as a polymer composed of 40 or fewer amino acids and explains that peptide products meeting the applicable drug definition are generally regulated as drugs under the FD&C Act unless they fall within another statutory category.³

The guidance focuses particularly on:

- hepatic impairment
- drug-drug interactions
- QTc prolongation
- immunogenicity
- pharmacokinetics
- safety

- efficacy

This is important because peptide therapeutics may have clinical-pharmacology characteristics that require specific evaluation rather than simple application of assumptions derived from conventional small molecules.³

6.5 New Drug Application

After successful completion of development, the sponsor may submit an NDA where appropriate. FDA explains that an NDA contains information necessary for the agency to evaluate the safety and effectiveness of a drug, including information concerning manufacturing, labeling and controls.⁷

For peptide therapeutics, this may include:

- pharmaceutical development
- analytical characterization
- manufacturing process
- impurity profile
- stability
- nonclinical studies
- clinical pharmacology
- clinical efficacy
- clinical safety
- proposed labeling

6.6 Alternative FDA Pathways

The U.S. regulatory system includes different statutory pathways depending on the product. These may include 505(b)(1) NDA, 505(b)(2) NDA and 505(j) ANDA. The appropriate pathway depends on the legal and scientific characteristics of the product and the information available to the applicant.

FDA's peptide-specific guidance issued in 2023 specifically addresses peptide products proposed for NDA submission under section 505(b).³

FDA has also been developing product-specific recommendations for generic peptide products. In July 2026, FDA announced 17 revised draft product-specific guidances covering selected peptide products, including products containing liraglutide, semaglutide, glucagon, calcitonin salmon and teriparatide.⁸

The guidance addresses scientific issues such as impurities, higher-order structure, biological activity and innate immune response testing for selected products.⁸

7. CDSCO Regulatory Framework for Peptide Therapeutics

7.1 New Drugs and Clinical Trials Rules, 2019

In India, the principal regulatory framework relevant to new drugs and clinical trials includes the New Drugs and Clinical Trials Rules, 2019 (NDCTR 2019). The rules were notified under the authority of the Drugs and Cosmetics Act, 1940.⁴

The official CDSCO regulatory database provides the NDCTR 2019 and subsequent amendments.⁴

7.2 Investigational New Drug Framework

CDSCO's Investigational New Drug Division plays an important role in the regulatory evaluation of investigational new drugs. CDSCO states that an

investigational new drug includes a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country, subject to the applicable regulatory definition.⁵

The IND application is used for:

- permission to conduct clinical trials
- import of investigational new drugs
- manufacture of investigational new drugs
- submission of required supporting documents and fees

Applications are processed through the SUGAM portal under the NDCTR 2019 framework.⁵

7.3 Clinical Trials in India

CDSCO's New Drugs Division processes applications for Phase I, Phase II, Phase III and Phase IV clinical trials under the NDCTR 2019 framework and applicable drug regulations.⁹

Clinical development therefore requires regulatory review before progression through the relevant stages. Clinical-trial oversight also incorporates ethics review. CDSCO maintains a regulatory system relating to the registration and oversight of Ethics Committees involved in clinical research.^{9,10}

7.4 New-Drug Approval in India

CDSCO's New Drugs Division processes applications for new-drug approval involving import, manufacture and marketing in India. CDSCO describes its functions as including processing applications for new-drug approval and clinical trials under the NDCTR 2019 and the Drugs and Cosmetics Rules, 1945.⁹

The regulatory assessment therefore considers whether the submitted evidence is adequate to support the proposed use and whether the product meets applicable quality, safety and efficacy requirements.

8. Comparative Analysis of FDA and CDSCO

Parameter	FDA – United States	CDSCO – India
Regulatory authority	U.S. Food and Drug Administration	Central Drugs Standard Control Organisation
Principal legal framework	FD&C Act and FDA regulations	Drugs and Cosmetics Act and associated rules
Major clinical-investigational	IND	IND/clinical-trial permission under NDCTR

on pathway		
Clinical phases	Phase I–III generally used for new drugs	Phase I–IV under applicable framework
Marketing application	NDA or applicable alternative	New-drug approval under applicable Indian pathway
Quality assessment	CMC and quality information	Pharmaceutical/quality information under applicable requirements
Clinical pharmacology	FDA guidance and product-specific considerations	Evaluated under applicable Indian regulatory framework
Ethics oversight	IRB requirements	Ethics Committee requirements
Electronic submission	FDA electronic submission systems	SUGAM portal
Post-marketing monitoring	Pharmacovigilance and FDA surveillance	Post-marketing surveillance/pharmacovigilance
Peptide-specific guidance	Specific draft guidance available	Peptides generally regulated within broader new-drug framework
Generic peptide	ANDA/product-specific	Applicable Indian abbreviated/modified

development	guidance where applicable	pathway depending on product
-------------	---------------------------	------------------------------

Source: Compiled from FDA and CDSCO regulatory sources.^{2–10}

9. Discussion

9.1 Similarities

9.1.1 Quality, safety and efficacy

Both regulatory systems require evidence demonstrating acceptable product quality, safety and efficacy before marketing authorization. For peptide therapeutics, quality evaluation is particularly important because the manufacturing process can influence the impurity profile and other product characteristics.

9.1.2 Preclinical development

Both systems require appropriate nonclinical evidence before extensive human exposure, subject to the applicable development pathway. Nonclinical studies provide information about pharmacology, toxicity and potential risks and help establish the scientific basis for human studies.

9.1.3 Clinical development

Both jurisdictions regulate clinical investigation before a new peptide can be broadly marketed. The U.S. system uses the IND framework, whereas India's system operates under the NDCTR framework.^{2,5}

9.1.4 Ethical review

Both systems require ethical oversight of clinical research. In India, CDSCO specifically maintains provisions relating to Ethics Committee registration and oversight.¹⁰

9.1.5 Post-marketing surveillance

Regulation does not end at approval. Both jurisdictions use post-marketing safety surveillance to identify safety signals that may emerge after broader patient exposure.

9.2 Differences

9.2.1 Regulatory terminology

The United States uses specific statutory pathways such as 505(b)(1), 505(b)(2) and 505(j). India uses its own classification and application framework under the Drugs and Cosmetics Act and NDCTR 2019. Consequently, an application pathway in one country cannot automatically be assumed to correspond exactly to a pathway in the other.

9.2.2 Peptide-Specific Regulatory Guidance

One of the important findings is the increasing degree of peptide-specific guidance in the U.S. system. FDA's 2023 draft guidance specifically addresses clinical pharmacology of peptide drug products. Furthermore, the 2026 revised draft product-specific guidances for selected generic peptides address specific scientific issues including impurities, higher-order structure and biological activity.^{3,8}

The Indian regulatory system regulates peptide products within the broader new-drug and clinical-trial framework, although specific scientific requirements

may apply depending on the product. Therefore, one distinction is that FDA has increasingly articulated peptide-specific scientific considerations through dedicated guidance documents.

10. Major Regulatory Challenges in Peptide Drug Development

10.1 Impurity Profile

Impurity control is one of the most important challenges in peptide development. Peptide synthesis may produce deletion sequences, truncated peptides, stereochemical variants, oxidation products and degradation products. The regulatory challenge is to identify relevant impurities, determine appropriate analytical methods and establish scientifically justified specifications. FDA's regulatory-science work specifically emphasizes analytical characterization of impurities in peptide products.⁶

10.2 Manufacturing Consistency

Peptide manufacturing must be reproducible. A change in raw material, synthesis process, purification, formulation, manufacturing scale or storage conditions can potentially affect the quality profile. Therefore, manufacturing process control is a major component of regulatory submissions.

10.3 Stability

Peptides may undergo degradation through several mechanisms depending on their structure and formulation. Potential changes can include hydrolysis, oxidation, aggregation, deamidation and conformational changes. Stability studies are therefore essential for determining shelf life and storage conditions.

10.4 Immunogenicity

Although peptides are smaller than many protein therapeutics, immune responses can be relevant depending on the molecule, formulation and patient population. FDA specifically identifies immunogenicity risk as an issue that may affect peptide pharmacokinetics, safety and efficacy.³

10.5 Pharmacokinetic Variability

Peptide pharmacokinetics can be influenced by route of administration, enzymatic degradation, renal clearance, hepatic processes, formulation, protein binding and patient characteristics. FDA's peptide guidance specifically discusses hepatic impairment and drug-drug interactions as clinical-pharmacology considerations.³

11. Regulatory Impact on Global Development

A pharmaceutical company developing a peptide product for both the United States and India must account for both regulatory systems from the early stages of development.

1. Product classification: The sponsor should establish how the peptide is legally classified in each jurisdiction.

2. Manufacturing strategy: Manufacturing processes should be designed with appropriate controls and analytical characterization.

3. Clinical strategy: Clinical development should consider the evidence requirements of both regulatory authorities.

4. Documentation: Regulatory documents should be prepared in a form that can support submissions in multiple jurisdictions while satisfying country-specific requirements.

5. Regulatory consultation: Early consultation can help identify potential regulatory issues before major clinical-development expenditure.

6. Post-approval requirements: The sponsor must also consider pharmacovigilance, manufacturing changes, labeling and lifecycle management after approval.

12. Opportunities for Regulatory Harmonization

12.1 Common Technical Standards

Greater convergence in analytical and quality standards could reduce duplication. Important areas include impurity characterization, peptide identity, purity, potency, biological activity, stability and manufacturing controls.

12.2 Regulatory Scientific Advice

Sponsors benefit when regulatory expectations are clarified before pivotal development begins. CDSCO's IND framework provides for pre-submission and post-submission meetings, while FDA also has established mechanisms for interaction between sponsors and the agency during development.⁵

12.3 Internationally Compatible Documentation

Common technical-documentation principles can facilitate preparation of regulatory submissions for several countries. This can reduce unnecessary duplication while retaining jurisdiction-specific requirements.

12.4 Development of Peptide-Specific Guidance

As peptide technologies evolve, regulators may increasingly need product-specific scientific guidance. The recent FDA product-specific draft guidances demonstrate this trend. Such guidance can help sponsors understand expectations regarding analytical characterization, impurity control, biological activity and comparative testing.⁸

13. Conclusion

Peptide therapeutics have become an important component of modern pharmaceutical development because of their high specificity and therapeutic potential. However, the development and regulation of these products involve scientific and regulatory challenges that differ in important respects from conventional small-molecule drugs. The comparative analysis of the FDA and CDSCO frameworks demonstrates that both jurisdictions share fundamental regulatory objectives: ensuring that pharmaceutical products meet appropriate standards of quality, safety and efficacy. The U.S. framework generally uses the IND pathway for clinical investigation followed by an NDA or another applicable marketing pathway.^{2,7} India regulates investigational new drugs, clinical trials and new-drug approvals primarily within the framework established by the Drugs and Cosmetics Act and NDCTR 2019.^{4,5,9} A significant finding of the comparison is that FDA has increasingly developed

specific scientific guidance addressing peptide drug products. The 2023 draft clinical-pharmacology guidance addresses hepatic impairment, drug-drug interactions, QTc prolongation and immunogenicity. FDA's 2026 revised draft product-specific guidances for selected generic peptide products further demonstrate the increasing regulatory importance of peptide-specific analytical and biological considerations.^{3,8} The Indian system, meanwhile, provides a structured regulatory framework for investigational new drugs, clinical trials and new-drug approvals through CDSCO and NDCTR 2019.^{4,5,9} The two systems therefore demonstrate substantial convergence in their fundamental objectives while retaining differences in statutory pathways, terminology, regulatory procedures and product-specific guidance. For pharmaceutical companies developing peptide therapeutics internationally, understanding these differences at the earliest stage can support more efficient development planning. Greater international alignment of technical requirements, improved regulatory communication, scientifically justified analytical standards and continued development of peptide-specific regulatory science could contribute to more predictable development pathways while maintaining appropriate standards of patient protection.

14. Limitations

22. The study is based primarily on secondary information.
23. Regulatory requirements may change through amendments, new guidance and regulatory decisions.
24. Peptide therapeutics represent a heterogeneous class, and requirements may differ according to the individual peptide, formulation, route of administration and indication.
25. The comparison represents a general regulatory analysis rather than product-specific regulatory advice.
26. The FDA peptide clinical-pharmacology document cited in this article is a draft guidance and is non-binding; FDA states that it is not for implementation in its draft form.
27. Specific regulatory submissions should therefore be evaluated against the current requirements applicable to the individual product.

15. References

1. Uploaded research document. Comparative study of regulatory requirements and approval pathways for peptide therapeutics in the USA and India. Background, objectives, rationale and methodology.
2. U.S. Food and Drug Administration. Investigational New Drug Application (IND) [Internet]. Silver Spring (MD): FDA; [cited 2026 Sep 29]. Available from: <https://www.fda.gov/drugs/types-applications/investigational-new-drug-application-ind>

3. U.S. Food and Drug Administration. Clinical Pharmacology Considerations for Peptide Drug Products: Guidance for Industry. Draft guidance. Silver Spring (MD): FDA; 2023 Dec. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-peptide-drug-products>
4. Central Drugs Standard Control Organisation. The New Drugs and Clinical Trials Rules, 2019. Ministry of Health and Family Welfare, Government of India. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/new_DC_rules/New%20Drugs%20and%20Clinical%20Trials%20Rules%2C%202019.pdf
5. Central Drugs Standard Control Organisation. Investigational New Drugs. Ministry of Health and Family Welfare, Government of India. Available from: <https://www.cdsco.gov.in/opencms/opencms/en/Drugs/Investigational-New-Drugs/>
6. U.S. Food and Drug Administration. FYs 2013–2017 Regulatory Science Report: Complex Mixtures and Peptides. Silver Spring (MD): FDA. Available from: <https://www.fda.gov/industry/generic-drug-user-fee-amendments/fys-2013-2017-regulatory-science-report-complex-mixtures-and-peptides>
7. U.S. Food and Drug Administration. New Drug Application (NDA) [Internet]. Silver Spring (MD): FDA. Available from: <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>
8. U.S. Food and Drug Administration. FDA Publishes Revised Draft Product-Specific Guidances for Certain Generic Peptide Products. July 28, 2026. Available from: <https://www.fda.gov/drugs/drug-alerts-and-statements/fda-publishes-revised-draft-product-specific-guidances-certain-generic-peptide-products>
9. Central Drugs Standard Control Organisation. New Drugs. Ministry of Health and Family Welfare, Government of India. Available from: <https://cdsco.gov.in/opencms/opencms/en/Drugs/New-Drugs/>
10. Central Drugs Standard Control Organisation. Ethics Committee. Ministry of Health and Family Welfare, Government of India. Available from: <https://www.cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/>