THE HDE CHECKLIST FOR FILING DECISION

Identification:

HDE Number: _____ Date Received:

Sponsor:

Device:

Procode:

Division/Branch:

Decision:

Recommendation: File _ Not File

Administrative Reviewer Signature: _____ Date:

Supervisory Signature: _____ Date:

THE HDE CHECKLIST FOR FILING DECISION

PART A - DEFICIENCIES TO BE INCLUDED AS REASONS FOR NOT-FILING THE HDE

Filing Review Elements	Yes Present Omission Justified	No Inadequate Omitted
I. Screening Information		
A. Applicant information		
1. Is the name and address of the applicant provided? (21 CFR 814.20(b)(1))	☐	☐
2. Has the applicant or authorized representative signed the HDE? (If applicant does not reside or maintain a place of business in the United States, the application must be countersigned by an authorized representative who does live or maintains a place of business in the U.S. Also the name and address of this person should be included) (21 CFR 814.104(a))	☐	☐
B. Are you aware of the applicant being the subject of an integrity investigation? If yes, consult the ODE integrity officer. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2, 21 CFR 814.42(e)(4) and Federal Register 90N-0332, September 10, 1991)	☐	☐
C. Is there a prior history with this device? For example, has a previously submitted PMA/HDE for this device been withdrawn? If yes, does the current HDE address any historical issues related to the reasons for the withdrawal such as fraud or safety?	☐	☐
II. Organizational and Administrative Elements (21 CFR 814.20, 21 CFR 814.104)		
A. Is the HDE sufficiently well organized to permit substantive review? (21 CFR 814.20(b)(2), table of contents, pages numbered, sections identified, six copies, and one copy which identifies trade secret or confidential information)	☐	☐

B. Is the device appropriate for review as an HDE?

1. Is there a copy or reference to the determination made by FDA's Office of Orphan Products Development that the device qualifies as a HUD? (21 CFR 814.104(c)(1)) ☐ ☐

2. Is there an explanation of why the device would not be available unless the HDE were granted? (21 CFR 814.104(c)(2)) ☐ ☐

   The applicant should provide information such as an estimate of the number of patients who would be required to generate data to support a full PMA and explain why such a study is not feasible or why the cost of conducting such a study could not reasonably be expected to be recovered (64 FR 33234).

3. Is there a statement that no other comparable device (other than another HUD approved under this subpart or under an approved IDE) is available to treat or diagnose the disease or condition? (21 CFR 814.104(c)(2)) ☐ ☐

C. Does the HDE contain an explanation of why the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use? (21 CFR 814.104(c)(3)) ☐ ☐

1. Does the explanation take into account the probable risks and benefits of the currently available devices or alternative forms of treatment? ☐ ☐

2. Does the explanation include a description, explanation, or theory of the underlying disease process or condition, and known or postulated mechanism(s) of action of the device in relation to the disease process or condition? ☐ ☐

III. Summary of Safety and Probable Benefit

(Blue Book Memo #P86-1, remember an HDE is exempt from the effectiveness requirements of sections 514 and 515 of the act and 21 CFR Part 814)

A. Are indications for use provided? (21 CFR 814.20(b)(3)(i)) ☐ ☐

B. Is an abbreviated device description provided? (21 CFR 814.20(b)(3)(ii)) ☐ ☐

C. Have alternative practices and procedures been included and described? (21 CFR 814.20(b)(3)(iii)) ☐ ☐

D. Is a description of the prior marketing history provided? (814.20(b)(3)(iv)) ☐ ☐

E. Is a summary of any study(ies) that may have been conducted provided? (21 CFR 814.20(b)(3)(v) and (vi) and 21 CFR 814.104(c)(4)(i))

1. Is a summary of the non-clinical laboratory studies and results provided? (21 CFR 814.20(b)(3)(v)(A)) ☐ ☐

2. Does the HDE include summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive) reasonably obtainable by the applicant that are relevant to an assessment of the risks and probable benefits of the device? (21 CFR 814.104(c)(4)(i)) ☐ ☐

IV. Technical Information

A. Device Characteristics and Manufacturing Section

1. Is a description of the device, pictorial representations, and materials specifications present, including the functional component(s) or ingredients? (21 CFR 814.20(b)(4)(i) and (ii)) ☐ ☐

2. Is a description of the principle of operation of the device (including components) and properties of the device relevant to clinical function present? (21 CFR 814.20(b)(4)(iii) and (iv)) ☐ ☐

3. **The Manufacturing Section may be waived for filing purposes and submitted later during the substantive review period;** OCS reviews for GMP issues; ODE reviews for safety issues.

   Has a description of the methods, facilities, and controls used in the manufacture, processing, packing, storage, and installation of the device been provided? (21 CFR 814.20(b)(4)(v)and Guidance for the Preparation of PMA Manufacturing Information) ☐ ☐

4. Performance Standards and FDA Guidance/ Guidelines: Has the applicant provided documentation to establish conformance with applicable standards and/or FDA guidance/ guidelines that are relevant to the safety of the device and that is known to or should reasonably be known to the applicant? (21 CFR 814.20(b)(5)) ☐ ☐

B. Nonclinical Laboratory Studies - as appropriate, are the following provided? (21 CFR 814.20(b)(6)(i))

1. Biocompatibility ☐ ☐

2. Microbiological ☐ ☐

3. Mechanical (wear, stress, etc.) ☐ ☐

4. Shelf life ☐ ☐

5. Analytical (for IVDs) ☐ ☐

6. Animal testing for safety-if appropriate, material specific and/or device specific ☐ ☐

7. A statement whether the nonclinical laboratory tests comply with the GLP regulation (Part 58), and if not, a brief statement of the reason for the noncompliance ☐ ☐

C. Clinical Experience and/or Investigations
(21 CFR 814.104(c)(4)(i))

1. Summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive), reasonably obtainable by the applicant, that are relevant to an assessment of the risks and probable benefits of the device ☐ ☐

2. **If a clinical investigation has been conducted to demonstrate safety, have the following been provided? (Note: Under 21 CFR 814.104(c)(4)(i), an HDE application is only required to contain the summaries, conclusion, and results listed above. Therefore, if the information listed below is not included, this is not a basis for refusing to file the application.)**

   a. a description of the protocol, subject inclusion/exclusion criteria, study period, and clinically significant safety endpoints ☐ ☐

   b. a description of study population including number of patients, device design used (if more than one), follow-up period, and demographics including gender considerations ☐ ☐

   c. a summary or data from subject evaluations and description of adverse events, e.g. adverse reactions, complications, discontinuations, complaints, failures, replacements, etc. ☐ ☐

d. if needed, a statistical analyses of the safety data (does OST Statistician recommend filing?) ☐ ☐

e. report forms for patients who died or were discontinued ☐ ☐

3. If there is an IDE for the device, has the data presented in the HDE taken into account any safety concerns raised in the IDE? ☐ ☐

4. If foreign clinical data are included, are data acceptable? (21 CFR 814.15(b) and 814.15(d)) ☐ ☐

5. Has the applicant submitted the financial certification and/or disclosure statements as required by 21 CFR Part 54? ☐ ☐

D. Labeling (21 CFR 814.20(b)(10); 21 CFR 814.104(c)(4)(ii) and Blue Book #P91-4)

1. Has appropriate draft labeling been submitted (e.g., Physician, Patient, Technical, etc.)? ☐ ☐

2. Does the labeling include the statement: "Humanitarian Device. Authorized by Federal law for use in the [treatment or diagnosis] of [specify disease or condition]. The effectiveness of this device for this use has not been demonstrated"? ☐ ☐

E. Amount Charged - Does the HDE include the amount to be charged for the device and, if the amount charged is more than $250.00, a report by an independent certified public accountant or an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the costs of the device's research, development, fabrication, and distribution? (21 CFR 814.104(c)(5)) ☐ ☐

V.	**Is there any other reason not addressed above which should be identified as a reason for not filing the HDE? If so, briefly explain.**	☐	☐

PART B - DEFICIENCIES TO BE INCLUDED IN THE "MINOR" SECTION OF THE NOT-FILING OR FILING BOILERPLATE LETTER

Additional Filing Review Elements	Yes	No
VI. Additional Administrative, Organizational and Regulatory Elements		
A. Do we need a device sample? If yes, has it been provided? (21 CFR 814.20(b)(9))	☐	☐
B. Is a bibliography provided? (21 CFR 814.20(b)(8)(i))	☐	☐
Have copies of key articles been provided and are English translations included, if appropriate?	☐	☐
C. If there are color additive considerations, has an attempt been made to document them? (21 CFR 814.20(f))	☐	☐
D. Is reference to applicable IDE(s) given? IDE#	☐	☐

PART C - ADDITIONAL CONSIDERATIONS

	Yes	No
VII. Additional Considerations		
A. Are there any special administrative issues? If so, explain. _____ _____ _____	☐	☐
B. Are there any precedent setting substantive issues? If so, explain. _____ _____	☐	☐

Draft Date: 24-APR-2000