Challenging the FDA:
An Overview of Administrative Remedies and Judicial Review

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This memorandum is designed to present an overview of the administrative and judicial remedies available to challenge an administrative action taken by the FDA, and in particular, CDRH. It will focus on the "plaintiff's side," that is, a private party involved with medical devices who, after exhausting all informal dispute resolution avenues, remains dissatisfied with CDRH actions such as:

- Denial of a 510(k) clearance
- Denial of permission to import a device
- Denial of pre-market device approval
- Disapproval of a product development protocol

This memorandum will not deal with the defense of administrative and judicial actions taken by FDA against a private party such as product seizures, injunctions and monetary penalties, nor will it cover challenges to FDA's regulations.

I. ADMINISTRATIVE REMEDIES.

A. Legal Background.

The Federal Food, Drug and Cosmetic Act, 21 USC 300, et seq. (the "FD&C Act"), the federal Administrative Procedures Act, 5 USC at Parts 5 and 7 ("APA") and FDA's administrative procedures regulations, 21 CFR at Parts 10 – 16, combine to offer a somewhat confusing array of remedies. The APA provides the basic statutory framework, with the regulations implementing that framework in the FDA context. The FD&C Act, however, provides certain specific remedies, again implemented by FDA's regulations. Finally, CDRH has issued a guidance document regarding these administrative remedies as they pertain to medical device disputes, Center for Devices and Radiological Health Appeals Processes - Guidance for Industry and Food and Drug Administration Staff, issued May 17, 2013 (herein, the "CDRH Guidance").

The basic scheme envisioned by the APA is that an administrative agency possessing what is referred to by the courts as a "quasi-judicial" authority, e.g., the authority to decide issues of compliance, licensure, etc., shall have a mechanism for according due process to parties affected by the agency's decisions. Administrative agencies are odd ducks, though existing under the Constitution parts of the executive branch of government, they often have "quasi-legislative" power (propounding regulations), normally exercised by the legislative branch of government, and quasi-judicial power, normally exercised by the judicial branch. Just as the judicial branch is Constitutionally-bound to follow due process, so are administrative agencies when using their quasi-judicial powers.

The components of due process basic to American law, consisting of notice of the government's action, the opportunity to contest the action, the ability to present evidence and argument, a determination by a person not involved in the original governmental action, and a reasoned decision. These are embedded in the APA, see, 5 USC 554, et seq. Judicial review of the agency's administrative adjudication is available to disgruntled parties, with a prescribed standard of review, all as discussed below in Section II of this memorandum.

Due process is a flexible requirement, with how much process being due in any given case depending on the interests at stake. Thus, the APA requires formal, trial-like evidentiary hearings only for matters where Congress by statute requires an evidentiary hearing (and perhaps where required by judicial precedent). Otherwise, an administrative agency may establish its own adjudicatory procedures so long as they do not conflict with the APA or judicial notions of due process. Congress and FDA have developed a multi-tracked, multi-level administrative adjudication process, with procedures varying depending upon the issues under consideration and the level of administrative review.

B. Procedural Aspects Common to All Remedies; Stay of Action.

FDA's various administrative review processes hold some features in common. First, any administrative review is made on "the file or files containing all documents pertaining to [the] particular administrative action, including internal working memoranda, and recommendations," 21 CFR Section 10.3. The submitting party may offer "graphs, simple analyses, or other minor clarifications …and should clearly identify the information as new and minor", according to FDA, but unless good cause is shown, no factual materials will be considered on review which were not before the original decision maker. The need to preserve appeal rights provides another reason to be as thorough as possible in an FDA regulatory submission.

One exception to this general rule is that new factual materials may result in the matter being referred back to the original decision maker for re-evaluation. 21 CFR Section 10.75.

A request for administrative review at any level should be clear and thorough, identifying the parties, specifying the agency action at issue, stating the relief sought (if possible, the exact language of the requested order), and providing the factual and legal basis for the relief. This includes contrary evidence, an important tactical point likely to be overlooked by litigators not accustomed to science-oriented reviews. The CDRH Guidance recommends an executive summary.

The filing of a request for administrative review does not automatically stay the administrative action during the pendency of the review. If a stay is desired, the requesting party may file a petition under 21 CFR Section 10.30, directed to the Commissioner. The stay must be requested within 30 days of the administrative action

and can be for a definite time or an indefinite time. Section 10.35. The petition for a stay must state the factual and legal grounds supporting it.

The Commissioner generally has the discretion to grant a stay, with some exceptions, "if it is in the public interest and in the interest of justice." Id. Interestingly, the Commissioner is *required* to stay the administrative action if *all* of the following apply:

> "(1) The petitioner will otherwise suffer irreparable injury; (2) The petitioner's case is not frivolous and is being pursued in good faith; (3) The petitioner has demonstrated sound public policy grounds supporting the stay; (4) The delay resulting from the stay is not outweighed by public health or other public interests." Id.

C. Supervisory Review.

The basic initial remedy is "supervisory review" under 21 CFR Section 10.75, under which the next highest organizational level reviews the decision complained of. The organizational hierarchy at FDA for medical devices is: Branch → Division → Office of Device Evaluation → CDRH → Commissioner of FDA. Thus, using the example given in the CDRH Guidance, a "Not Substantially Equivalent" letter typically issues from a division, meaning that a request for supervisory review would be directed to the Office of Device Evaluation.

The CDRH Guidance contains a suggested format for a request for supervisory review. CDRH generally considers requests for supervisory review to be timely if filed within 60 days of the administrative action complained of, unless the action is a "significant decision" subject to 21 USC Section 360g–1 (discussed below).

The requestor may seek an in-person meeting or a teleconference meeting. CDRH believes that meetings should not normally be needed for actions that are not "significant decision", and that reviews of such actions can be had on the papers. If a meeting is ordered,

> "One or more members of the review team and Branch Chief or other appropriate member of management should be present at the meeting at the invitation of the review authority. However, since the meeting is the submitter's opportunity to make its case directly to the review authority, interactions between the review team and the submitter should be managed by the review authority to ensure that the submitter has an unfettered opportunity to state its case." CDRH Guidance, section 2.3.

Other than for reviews of "significant decisions", there is no time deadline for the issuance of a decision letter by the reviewer. A decision letter will the basis for the request for review, conveys the decision of the review authority, explains the basis for the decision, and describe options for further review or appeal.

1. Special Rules for "Significant Decisions".

21 USC Section 360g–1 applies special rules supervisory reviews involving "significant decisions", typically 510(k) submissions, PMA applications or IDE applications. The request for review is due not later than 30 days after the administrative action. The reviewing party shall schedule any requested in-person or teleconference review within 30 days, and issue a decision not later than 45 days after the request is made, or 30 days after an in-person meeting or teleconference is held. The decision shall "provide a substantive summary of the scientific and regulatory rationale… including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion."

Upon completion of a supervisory review, 21 CFR 10.45 states FDA's position that a dissatisfied party may not go directly to court, but must first pursue the next level of administrative review.

2. Special Rules for Scientific Disputes.

Pursuant to Section 515 of the FD&C Act, and 21 CFR 814.44, denials of PMA approvals, issuance of conditional approvals, and revocations of PMA approvals and product development protocols are entitled to be submitted for adjudication before a scientific advisory panel. According to the CDRH Guidance, this provision of Section 515 "has been implemented by CDRH with the establishment of the Medical Devices Dispute Resolution Panel (DRP)," by which scientific disputes can be heard at the supervisory review stage. FDA's procedures for this process are not specified in the CFR, but instead, in Section 3 of the CDRH Guidance.

The DRP process begins by the disgruntled party requesting supervisory review of the issue at the CDRH level. CDRH has the discretion to invoke the DRP process or not. If not, then supervisory review by CDRH will proceed as described above.

Normally, a party is expected to have taken the dispute through supervisory review at a level below CDRH, and the scientific issue should already have been the subject of an FDA scientific advisory committee meeting. CDRH has the discretion to waive these prerequisites.

DRP proceedings will be conducted in much the same manner as advisory panel meetings, with the main difference that a DRP proceeding "is an adversarial process in which the Center defends a decision that has already been made." The panel may question the parties. The panel is to reach an initial decision and prepare "a Statement of Findings and a Recommendation on the disposition of the issues under consideration, including any minority views. These documents will be issued to the Center Director or FDA Commissioner, as applicable, who will make the final decision."

The CDRH Guidance at Section 2.4 also offers a less-elaborate mechanism for supervisory reviews of "highly complex scientific and clinical matters." The requestor may ask that the review authority refer the matter to one or more external Subject Matter Experts, to evaluate the matter in dispute and provide advice to the review authority. CDRH may also make this referral on its own initiative. In this process the review authority will consult with the requestor in framing the issues and evidence and in designating the Subject Matter Experts to conduct the evaluation. Technically, this remedy is not limited to PMA-related disputes, however, it can be expected that most "highly complex scientific and clinical matters" would be generated in the PMA context.

Since Dispute Resolution Panels and Subject Matter Experts only issue initial decisions or recommendations to the Director of CDRH on scientific questions, their actions do not constitute final agency actions for purposes of judicial review.

3. Special Procedure for Importation Disputes.

Subpart E of 21 CFR Part 1 provides administrative remedies particular to disputes over the importation of regulated goods.

If, based upon a product sampling or otherwise, it appears that a medical device may be subject to refusal of admission to the US, the director of the FDA district having jurisdiction over the port of entry shall notify the owner or consignee of the device that they "shall have an opportunity to introduce testimony." Section 1.94. The notice shall specify the time and place for the hearing. Testimony may be oral or written – one suspects that many such "hearings" are had solely on the papers -, and in all events must be limited only to the issue of the device's admissibility to the US. Id.

Sections 1.95, et seq., allow the owner or consignee to apply for permission to relabel or recondition the device to bring it into compliance with US law. If such permission is sought, the owner's or consignee's testimony must contain evidence supporting the application to recondition or relabel. Section 1.94.

In light of the discussions elsewhere in this memorandum, I believe that a party, whose device is, after this process, still denied admission to the US, will need to exhaust the remedy of at least one level of supervisory review before availing itself of one of the more formal administrative remedies.

D. Citizen Petition.

The next step after the appropriate avenues of supervisory review have been exhausted is a "citizen petition" under 21 CFR Part 10, in which the petitioner presents his case in writing to the Commissioner of the FDA. As will be discussed later, an informal "Regulatory Hearing Before the FDA" may be had on certain petitions (Part 16); a formal public hearing on the petition may be had under Part 12 in certain specific cases; and public hearings may be had under certain circumstances before a "board of inquiry" (Part 13), a scientific advisory board (Part 14), or the Commissioner of FDA (Part 15).

Administrative actions challengeable by petition may be characterized as every act, including the refusal or failure to act, by an FDA employee, involving the administration the FD&C Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

The process of challenging an administrative action begins with the aggrieved party filing a petition to the Commissioner "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." Section 10.25.

The petition may be submitted electronically, or by mail or in person, in duplicate, to the Division of Dockets Management, Food and Drug Administration, Rockville, MD. If mailed, it is deemed filed on the postmark date. Note that petitions are signed with the following attestation:

> The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Petitions must generally be filed within 30 days of the issuance of the original administrative action. Therefore, it is possible that an aggrieved party, in order to preserve appeal rights, may need to put the dispute on two tracks, a supervisory review and concurrently a petition to the Commissioner. The CDRH Guidance states that filing a petition usually results in the suspension and supersession of the supervisory review.

A petition may be amended or withdrawn without prejudice until either it is adjudicated or referred to a hearing.

The ordinary method of adjudicating petitions is for the Commissioner to designate someone in the organization to resolve the matter. Adjudication is based upon the administrative record, as that term is defined in Sections 10.3 and 10.30.

The Commissioner may select any reasonable method of hearing the matter; the regulation mentions conferences, meetings, discussions, correspondence and public hearings. Telephone conferences are used as well.

A petition involving medical devices must receive an adjudication within 180 days of its filing. Such adjudications are final agency actions for purposes of judicial review.

E. Administrative Reconsideration.

The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person" to reconsider "part or all of a decision of the Commissioner on a" citizen petition. (All quotations here are from 21 CFR Section 10.33.) The petition for reconsideration must be filed with the Division of

Dockets Management in a form specified by the regulation, and filed "no later than 30 days after the date of the decision involved," unless the Commissioner extends the filing date for good cause.

The grounds for reconsideration "must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. A party who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision.

The Commissioner *may* grant reconsideration when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner *shall* grant reconsideration in any proceeding if the Commissioner determines *all* of the following apply:

> "(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered, (2) The petitioner's position is not frivolous and is being pursued in good faith, (3) The petitioner has demonstrated sound public policy grounds supporting reconsideration, (4) Reconsideration is not outweighed by public health or other public interests."

F. Public Hearings.

21 CFR Parts 12 and 13 provide for public hearings of different sorts on various specified matters. Exhibit 1 sets forth the tables of contents for both parts, as well as for Part 16. 21 CFR Part 14 provides for a public hearing before an advisory committee, but inasmuch as CDRH deems the Dispute Resolution Panel to be its replacement, it will be discussed here only briefly. Finally Part 15 provides for a public hearing before the Commissioner.

1. Part 12—Formal Evidentiary Public Hearing.

Pursuant to Section 515 of the FD&C Act and 21 CFR 10.50, denials of PMA approvals, issuance of conditional approvals, revocations of PMA approvals and product development protocols may be challenged at a formal evidentiary hearing. Such a hearing may also be called by the Commissioner when "the Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA." Section 12.1.

Proceedings are initiated by a party via a petition for reconsideration under Section 10.30, to be filed within an absolute deadline of 30 days of the issuance of notice of the action in question and the concomitant opportunity to request a hearing. Section 12.21.

Despite the FD&C Act's seemingly categorical language, there is not always an absolute right to a hearing. The petitioner must set forth its objections to the administrative order, requesting a hearing on each objection, and must supply the items of information spelled out in the regulation. Section 12.22. The Commissioner will then decide whether to order a Part 12 hearing or some other process, utilizing the criteria enumerated in Section 12.24, and publishing the decision in the Federal Register.

A party entitled to a hearing under Part 12, may waive it and request a hearing before a Public Board of Inquiry under Part 13, a hearing before a public advisory committee under Part 14, or a hearing before the Commissioner under Part 15 (all discussed below). This request must be made before the Commissioner determines the right to a hearing under Part 12, and if the request is granted, it is irrevocable. Section 12.32.

At this point, I will not restate the exhaustive procedures for a formal evidentiary hearing, whose outline can be found in Exhibit 1, but will highlight items of interest to the practitioner:

- A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer.
- A party may appear by counsel or a representative.
- Hearings are open to not only public attendance, but also public participation, so long as the procedures and deadlines for participating are followed.
- Parts of the hearing may be closed, and the hearing record sealed, to protect information related to privacy and certain trade secrets. See, Section 10.20.
- There is live testimony, taken under oath.
- "Official notice" on the same lines as judicial notice[1], is permitted.
- Evidence is excludable only if "irrelevant, immaterial, unreliable, or repetitive."
- Pre-hearing discovery is allowable in the discretion of the presiding officer.
- A far-reaching pre-hearing conference serves the purpose of FRCP Rule 9[2] exchange, expert witness qualification, hearing on sua sponte summary judgment[3] (for which interlocutory review by the Commissioner is available), and limine motions[4].
- At the conclusion of evidence, the parties are to submit proposed findings of fact and conclusions of law.

Section 21.120 provides that the presiding officer issues an initial decision, with an objection period, and an opportunity to appeal it to the Commissioner. The Commissioner's review on appeal is de novo. If the initial decision is not objected to or

[1] Judicial notice allows the court to take into account certain facts outside of evidence otherwise admissible, as specified in FRE Rule 201: "a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."
[2] Mandatory exchange of information at the commencement of a case.
[3] A decision based upon the record so far, in which there is a finding that there exists no dispute as to material facts.
[4] Motions to exclude evidence, limit testimony, etc.

appealed, it becomes the decision of the Commissioner. The Commissioner's decision is published in the Federal Register, and constitutes a final agency action ripe for judicial review.

2. Part 16 - Regulatory Hearing Before the FDA.

21 CFR Part 16 provides for an informal hearing, curiously named a "Regulatory Hearing," before a hearing officer appointed by the Director of CDRH[5] in instances where, 1) a statute or regulation specifically provides for an "opportunity for a hearing," or 2) the Director, in the Director's discretion, "to obtain additional information before making a decision or taking action". In the latter case, the Director may sua sponte initiate a hearing, or may grant the request of a party for one. A Part 16 hearing is often a substitute for the more formal Part 12 process.

Common examples of a required opportunity for a hearing are denials of 510(k) clearances and denials of PMA approvals. Statute and regulation require an opportunity for a hearing in dozens of other instances as well, all neatly listed in the regulations.

Part 16 does not apply to refusals to allow the importation of medical devices; such matters are to be resolved via the separate informal hearing process discussed previously.

Part 16's hearing process begins with a notice from the Director that the private party has a given number of days within which to formally request a hearing. If none is requested, no hearing will be had.

The place of hearing will be as agreed to by the party and a presiding officer appointed by the Director.

The rules of procedure for regulatory hearings will not be repeated here, but Exhibit 1 shows the table of contents for Part 16, as well as comparing the same to tables of contents for Parts 12, 13 and 15. I highlight here some items of note:

- "[T]he presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue." Such a summary decision is reviewable by the Commissioner. Section 16.26.
- The hearing is informal in nature, with no requirement that the rules of evidence be followed. The extent of procedures depends somewhat upon whether the hearing is one required by statute or discretionary.

[5] Technically, the regulation refers to the Commissioner of FDA, but the guidance document mentioned above indicates that the Commissioner has appointed the Director of CDRH to administer most medical device disputes under Part 16. Accordingly, I will read the regulations as naming the Director of CDRH in instances where the Commissioner is referred to.

- The hearing is open to the public, except when the Commissioner determines that all or part of it should be closed to protect privacy or trade secrets.

The presiding officer is to issue a report - what amounts to a tentative ruling -, upon which the parties may comment before a final decision issues. It appears that the final decision is to be rendered by the Commissioner, or CDRH as the Commissioner's designee, which would then constitute a final administrative action purposes of judicial review.

3. Part 13—Public Hearing Before A Public Board of Inquiry.

It will be recalled that scientific disputes pertaining to PMA devices may be submitted to CDRH's Medical Devices Dispute Resolution Panel in the supervisory review stage of FDA's administrative dispute resolution process. 21 CFR Part 13 applies the concept of a review by scientific experts to a final, regulatory adjudication of disputes where, 1) a party is entitled to an evidentiary hearing under Part 12, and waives such a hearing in favor of a hearing before a board of inquiry, or 2) "the Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a [board of inquiry] with respect to any matter before FDA." Section 13.1.

The composition of the board is interesting. First, "all members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered". Section 13.10. Second, both the petitioner and CDRH submit to the Commissioner the names of 5 persons nominated to serve as members of the board. There is a right of comment. The Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by CDRH and one from the list submitted by the petitioner. "The Commissioner may choose the third member from any source. That member is the Chairman of the Board."[6] Section 13.10.

Alternatively, CDRH and the petitioner, may, with the approval of the Commissioner, agree that a standing advisory committee listed in 21 CFR Section 14.80 constitute the board, or that another procedure is to be used for selection of the members of the board, or that the board consists of a larger number of members. Id.

As with my discussion of hearing procedures under Parts 12 and 16, above, I will merely highlight procedural items of note, and otherwise refer the reader to Exhibit 1 for more details.

- The elaborateness of procedures depends upon whether the Part 13 hearing is a formal evidentiary hearing; if so, the procedures are more extensive. See, e.g., Section 13.5.
- "The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial." Section 13.30.

[6] This procedure is reminiscent of how a panel of arbitrators is assembled in commercial arbitrations.

- Members of the board may question the participants.
- The hearing is informal and the rules of evidence do not apply.
- The hearing is open to the public, except to the extent needed to protect privacy or confidential information.
- The board may consult with any person who it concludes may have information or views relevant to the issues.
- Legal questions are referred to the chief counsel for FDA for resolution.

The Board will prepare a decision that will include specific findings, evidentiary support, and reasoned conclusions. Any member of the Board may file a separate report stating additional or dissenting views. These are conveyed to the Commissioner for review and conversion into a final order.

21 CFR Section 12.32 contains an oblique assertion of FDA's position that the decision of the board of inquiry will be treated in the same manner as an initial decision of a hearing officer under section 12.120 of Part 12, discussed above. Thus, FDA views the decision of the board of inquiry is interim, with only the Commissioner's final decision being the subject of judicial review. This view is consistent with the cases decided under the APA.

4. Part 14—Public Hearing Before A Public Advisory Committee.

As mentioned above, Section 515 of the FD&C Act grants PMA applicants the right to have certain disputes heard by a public advisory committee[7]. These are governed by 21 CFR Part 14. It expands the right of a hearing by a public advisory committee beyond Section 515, to circumstances where, 1) a party is entitled to an evidentiary hearing under Part 12, and waives such a hearing in favor of a hearing before an advisory committee, or 2) "the Commissioner concludes as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee…to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee." Section 14.1.

Because advisory committee proceedings "are generally lengthy and resource-intensive for both petitioners and FDA," CDRH has instituted the Dispute Resolution Panel as its own implementation[8] of the right to a hearing granted by Section 515 of the FD&C Act as discussed above. For this reason, and because, according to CDRH, Section 14 has "rarely been invoked" as a dispute-resolution mechanism, I will not discuss it further.

[7] These are established by FDA regulation, and must function in accordance with the Federal Advisory Committee Act, 5 USC Appendix.

[8] The propriety of implementing a provision of the FD&C Act via a guidance document versus a formal regulation is open to question, US v. Utah Medical Products, Inc., 2005 Westlaw 2716299 (D.UT., 2005), but that is beyond the scope of this memorandum.

5. Part 15—Public Hearing Before the Commissioner.

Part 15 provides for public hearings before the Commissioner of FDA in medical device disputes where, 1) the dispute pertains to the custom device permits, 2) the petitioner is entitled to a formal evidentiary hearing under Part 12, but elects in lieu thereof to have the dispute heard by the Commissioner, and 3) "the Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the" FDA. Section 15.1.

While the regulation is phrased in terms of a "hearing before the Commissioner," the Commissioner is permitted to designate someone to either hear the matter alone or as the presiding officer of a panel of experts. If the experience with Part 16 is any indication, it might be anticipated that authority would be devolved to the director of CDRH.

As with the other substitutes for a Part 12 formal evidentiary hearing, the procedures under Part 15 are more elaborate for such a hearing than for other types. Even so, the hearing is to be informal, and the rules of evidence do not apply. Section 15.30.

The regulation envisions a give-and-take between the hearing officer/panel, and a pre-hearing written submission may be required to enable questioning by the officer/panel. Section 15.20.

The remaining procedures are set forth in the regulations, with a listing thereof to be found in Exhibit 1.

II. JUDICIAL REVIEW.[9]

A. The Basics.

Consistent with the notion of checks and balances among the branches of government, The APA provides that decisions by administrative agencies are subject to review by the courts upon petition by a person "adversely affected or aggrieved by agency action…." 5 USC Section 702.

Jurisdiction and venue, unless specified otherwise in the FD&C Act, is in the United States District Court of the district in which the device maker has its principal place of business. 28 USC Section 1402. In matters involving a 510(k) submission, a PMA application or an NDE submission, the FD&C Act allows suit to be commenced in the appropriate United States Circuit Court. 21 USC Section 360g. In the event a Utah device maker filed suit against FDA in Denver, such a suit could take two paths. The 10th Circuit could actually try the case and render a judgment, as happened in the D.C.

[9] In many instances of the case law discussion in this section, I have used and modified summaries of the cases prepared by West Publishing Company's Westlaw service. While this is never good practice in court submissions, I think it is acceptable here for discussing general principles of law.

Circuit in Cytori Therapeutics, Inc. v. FDA, infra. Or, the 10th Circuit could one of the District Judges in Salt Lake City as a special master to try the case, with the 10th Circuit adopting his/her "recommended decision" as its judgment. See Rule 48, FRAP.

The statute of limitations requires that suite challenging an agency action be filed within 6 years of the date of the final agency action. 28 USC Section 2401; Alaska v. USDA, 932 F.Supp.2d 30 (D.D.C., 2013). However, if the suit seeks equitable[10] remedies such as injunctive relief or a declaratory judgment[11], then the equitable defense of laches[12] applies.

B. Final Agency Action.

Only "final" agency actions are reviewable. 5 USC Section 704. The finality of an agency action is determined by a two-part test: First, the action under review must mark the consummation of the agency's decision making process — it must not be of a merely tentative or interlocutory nature. Second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow. National Association of Home Builders v. Norton, 415 F.3d 8, 13 (D.C.Cir., 2005) (citations and internal quotation marks omitted).

This language is admittedly very general. Examples of where the line between final and not final FDA actions was drawn are:

FDA's interpretation of the Medicare Modernization Act in the context of making delisting decisions for generic blood pressure drugs, constituted an adjudication, and thus was "final agency action" subject to review. Teva Pharmaceuticals USA, Inc. v. Sebelius, 638 F.Supp.2d 42 (D.D.C., 2009), rev'd. other grounds, 595 F.3d 1303 (D.C.Cir., 2010).

A complete response letter (CRL) issued by FDA regarding biologic product Provenge which was intended to treat metastatic prostate cancer, was not a "final agency action," since the CRL was not the consummation of the decision making process for Provenge, but rather was an interlocutory step in FDA's administrative process to assure sufficient data to establish safety and effectiveness prior to the approval of a biologics license application; the CRL did not determine any legal rights or obligations. CareToLive v. Eschenbach, 525 F.Supp.2d 938 (S.D., Ohio, 2007).

An informal letter issued by FDA, apparently without its having first conducted any tests, asserting that a certain product was a new drug as to which plaintiff had failed to file and obtain approval of a new drug application, requesting plaintiff to contact the agency, and

[10] Remedies historically granted by English courts of chancery versus courts of law, a subject beyond the scope of this memorandum.
[11] A judgment declaring the rights among the parties, here for example, that a prospective action of FDA would contrary to law or regulation.
[12] Unreasonable delay, prejudicial to the agency, even though the statute of limitations may still allow the suit.

threatening invocation of regulatory sanctions should plaintiff fail to respond, was not a "final agency action". IMS Ltd. v. Califano, 453 F.Supp. 157 (C.D.Cal.,1977)

Food and Drug Commissioner's order for decertification of drugs constituted a final agency action. Upjohn Co. v. Finch, 303 F.Supp. 241 (W.D.Mich.,1969).

Even though an FDA action might technically be "final," it still might not be ripe for judicial review. In AstraZeneca Pharmaceuticals LP v. FDA, 850 F.Supp.2d 230 (D.D.C., 2012), AstraZeneca's claim that FDA wrongly denied its citizen petition requesting that FDA refrain from granting final approval to competing generic antipsychotic drugs was held to not be ripe for review because, even though the denial of a petition is normally a final, reviewable agency action, in this case FDA had not made a concrete determination on the underlying generic drug applications, which rendered premature judicial review of the denial of AZ's petition.

C. Exhaustion of Administrative Remedies.

Allied to the notion of a final administrative action is the judicially-created requirement that the complaining party first exhaust its administrative remedies before coming to court. Thus the plaintiff in IMS Ltd. v. Califano, supra, was held under the facts discussed above not to have exhausted its administrative remedies, since the plaintiff had available the procedure of a citizen petition to the Commissioner of the FDA.

As has been seen in the discussion under Part I of this memorandum, FDA's regulations often will clearly state the agency's stance on whether a given action is "final" and ready for judicial review.

D. Standard of Review.

Judicial review of a final FDA action is not de novo[13]. Instead, the APA specifies the following deferential standard of review, under which the agency's decision is to be upheld unless it is:

"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
"(B) contrary to constitutional right, power, privilege, or immunity;
"(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
"(D) without observance of procedure required by law;
"(E) unsupported by substantial evidence in a case" where a formal hearing is held. 5 USC Section 706.

De novo review to determine if agency action was unwarranted by the facts is authorized when the action is adjudicatory in nature *and* the agency's fact-finding procedures are inadequate, or when issues that were not before the agency are raised in a proceeding to enforce a non-adjudicatory agency action. Citizens to Preserve

[13] I.e., where the court hears the matter anew, without reference to the agency's prior decision.

Overton Park, Inc. v. Volpe, 91 S.Ct. 814 (1971). Whether a particular FDA action runs afoul of the Overton Park rule needs to be determined on a case-by-case analysis of the fact-finding procedures actually used by FDA in that case.

Within the arbitrary and capricious standard, agency factual findings will be upheld if they are supported by substantial evidence, Bear Lake Watch, Inc. v. FERC, 324 F.3d 1071 (9th Cir., 2003), which consists of "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. If the evidence is susceptible of more than one rational interpretation," the court must uphold the agency's findings. Id., 324 F.3d at 1076.

In assessing whether an FDA action was arbitrary and capricious, courts give a high level of deference to an agency's evaluations of scientific data within its area of expertise. A.L. Pharma, Inc. v. Shalala, 62 F.3d 1484, (D.C. Cir., 1995). Judgments as to what is required to show safety and efficacy fall squarely within the ambit of the FDA's expertise and merit deference from the courts. Sanofi-Aventis U.S. LLC v. FDA, 842 F.Supp.2d 195 (D.D.C., 2012). Similarly, in the context of generic drugs, FDA is to be accorded judicial deference regarding the criteria by which the chemical identicality of two substances it to be determined, and FDA's methodology will be upheld if it is supported by a scientifically rational basis. Id. The implications of this principle for the "substantial equivalence" of medical devices is obvious.

Thus, where FDA's determination that medical devices which used fat tissue as source of stem cells in lab analysis and potentially regenerative medicine were not substantially equivalent to devices which extracted stem cells from blood or bone marrow was reasonable and reasonably explained, FDA's conclusion that that those devices met neither the "intended use" nor the "technological characteristics" criteria for substantial equivalence was not arbitrary and capricious. Cytori Therapeutics, Inc. v. FDA, 715 F.3d 922 (D.C.Cir., 2013). The intended use was found by FDA not to be substantially similar to that of the predicate, because extracting cells from fat is different from extracting cells from blood, specifically, a device designed specifically to process fat is not intended for the same use as a device designed to process some other form of tissue. Nor were the devices' technological characteristics substantially similar to those of the predicate, because the devices required new technology both to break down the fat tissue and to harvest the useful cells by separating heavier stem cells from fat tissue.

In US v. Snoring Relief Labs, Inc., 210 F.3d 1081 (9th Cir., 2000) a manufacturer had defended its marketing of an anti-snoring mouthpiece without a prescription on the ground that FDA acted arbitrarily and capriciously in deeming it a Class III device. FDA's Dental Devices Branch of the Office of Device Evaluation enlisted a doctor of dental surgery who served as Senior Regulatory Review Officer, to compare the device prescription-only, anti-snoring mouthpieces on the market. The reviewer concluded that the device should require a prescription because, (1) would require the patient to distinguish between simple snoring and obstructive sleep apnea, a potentially life-threatening condition; and (2) would require the patient to determine if she has any temporomandibular joint disease that would not permit the use of an oral appliance.

Based upon this evidence, the court held that FDA's classification of the device was not arbitrary and capricious.[14]

With the deference given to FDA's scientific evaluations, it is therefore not surprising that the bulk of "arbitrary and capricious" rulings against FDA pertain to non-scientific issues. For example, FDA, having accepted an NDA applicant's representation that a patent to be listed in FDA's Orange Book covered the use of an epilepsy drug to treat neurodegenerative diseases, acted arbitrarily and capriciously when it required a generic drug applicant to certify that generic drug would not infringe the NDA applicant's patent, when under the regulations, the generic drug applicant should have been allowed to certify that the patent was not claiming use for which the generic drug applicant was seeking to market drug. Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877 (D.C.Cir., 2004).

FDA acted arbitrarily and capriciously when it appointed members with financial conflicts of interest to the Tobacco Products Scientific Advisory Committee, and thus, agency fatally tainted the composition of the committee and its report on menthol cigarettes. Several appointees had consulted for manufacturers of nicotine replacement therapy drugs and other smoking-cessation drugs that would benefit from a ban or restriction on menthol cigarettes and dissolvable tobacco products or had testified in lawsuits against tobacco product manufacturers, before, during, and after serving on the advisory committee. The court remanded the matter to FDA for appointment of a newly-constituted, interest free, panel of authorities consistent with applicable ethics laws. Lorillard, Inc. v. FDA, 2014 WL 3585883 (D.S.C., 2014).

FDA decisions that are not supported by law or regulation are arbitrary and capricious. Thus, FDA acted arbitrarily and capriciously by allowing shipments of a misbranded and unapproved new drug to enter United States for use in state lethal injection protocols for death row inmates' executions; the drug had neither been listed with FDA, covered by an approved NDA, nor in compliance with regulations pertaining to investigational new drugs. Beaty v. FDA, 853 F.Supp.2d 30 (D.D.C., 2012).

See also Purepac Pharmaceutical Co. v. Thompson, supra.

A less clear case is one in which FDA adopts one interpretation of a statute and the plaintiff another. The rule in this instance is that, in reviewing an agency's interpretation of a statute that it is charged with administering, if the intent of Congress is clear, that is the end of the matter; the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. However, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a reasonably permissible construction of the statute, and if so, it is to be upheld. Barr Laboratories, Inc. v. Thompson, 238 F.Supp.2d 236 (D.D.C., 2002).

[14] This case summary does not convey the irredeemable mess created by the device maker for itself. It is a tour de force of how NOT to conduct one's regulatory affairs.

E. Evidence on Judicial Review.

By the very nature of the arbitrary and capricious standard, the administrative record, that is, the totality of materials before the administrative body at the time of its decision, is typically the sole basis for the reviewing court's decision. Citizens to Preserve Overton Park, Inc. v. Volpe, supra. However, the record supplied by the agency must contain *all* such materials, and may be supplemented if they have been omitted. Portland Audubon Soc. v. Endangered Species Committee, 984 F.2d 1534 (9th Cir., 1993). Thus, sometimes discovery is permissible to determine whether the administrative record submitted to the court is in fact complete, if there is some indication that it might not be. NVE, Inc. v. Department of Health and Human Services, 436 F.3d 182 (3d Cir., 2006). There are other narrow grounds for admitting materials not in the administrative record, e.g., documents excluded from consideration by the agency, where the contention on review is that the agency *should* have considered them, Fund for Animals v. Williams, 391 F.Supp.2d 191 (D.D.C., 2005), or that there were clerical errors in collating and photocopying the record.

Evidence outside the record that the administrative agency acted with bad faith toward the plaintiff is of course permitted, but this type of issue is beyond the scope of this memorandum.

F. Judicial Stay.

5 USC Section 705 allows the court reviewing an administrative agency action, "on such conditions as may be required and to the extent necessary to prevent irreparable injury,…issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." FDA takes the position that a stay should be sought from it before it is sought from the court. 21 CFR 10.45.

The standards for a stay (sometimes referred to by the courts as a preliminary injunction) pending judicial review under the Section 705 are the same as the standards for issuance of a preliminary injunction under the Federal Rules of Civil Procedure. Courts commonly look at three main factors: (1) the moving party's likelihood of success on the merits, (2) the threat of irreparable harm or injury to the moving party absent the stay, (3) whether the public interest calls for a denial of the stay. Hamlin Testing Laboratories, Inc. v. United States Atomic Energy Commission, 337 F.2d 221 (6th Cir., 1964). The burden is on the moving party to establish that a preliminary injunction is appropriate. No single factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance they weigh towards granting the stay.

Regarding the required showing of irreparable injury if a stay is not granted, the availability of a money damage action against the government militates against a finding of irreparable injury, although it is hard to see what kind of realistic money damage remedy a wronged device manufacturer would enjoy.

Regarding the public interest, in the context of a regulation, it was held that if FDA "believes that a suit…will significantly impede enforcement or will harm the public interest, it need not postpone enforcement of the regulation and may oppose any motion for a judicial stay on the part of those challenging the regulation….It is scarcely to be doubted that a court would refuse to postpone the effective date of an agency action if the Government could show…that delay would be detrimental to the public health or safety." Abbott Laboratories v. Gardner, 387 U.S. 136, 156 (1967).

G. A Final Note on Tactics.

Prosecuting an APA action against FDA can have unintended consequences for the defense against an FDA injunction or seizure action. Normally, since the latter are heard originally by the court, the defendant is not subject to the arbitrary and capricious standard, nor is the defendant limited to the administrative record. However, when an APA claim is asserted as a counterclaim in the injunction or seizure action, the FDA's complaint may be defended only under the deferential arbitrary and capricious standard. US v. Snoring Relief Labs Inc., supra. Lesson: Think before acting; don't automatically file a counterclaim or assert "arbitrary and capricious" agency action as an affirmative defense to an FDA complaint.