UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK, Plaintiff, -v- UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	20 Civ. 689 (AJN)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

Defendant U.S. Food and Drug Administration ("FDA" or "Defendant"), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in support of its motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

Plaintiff Informed Consent Action Network ("ICAN" or "Plaintiff"), a frequent requester to the FDA and other agencies, made a request under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, seeking the disclosure of certain records related to clinical trials underlying FDA's approval of Engerix-B, a hepatitis B vaccine licensed in 1989.

FDA promptly responded to ICAN's request and sought further clarification. ICAN clarified that it was seeking reports of pre-licensure clinical trials, but stated that its request was limited to those trials that that "had a safety review period longer than seven days following administration" of the Engerix-B vaccine. FDA explained that it was unable to search for records in the manner requested by ICAN, because of the undefined term "safety review period" and because clinical trial records are not organized in this way. Instead, FDA offered to broaden the scope of ICAN's request so that the agency would process and produce all pre-licensure clinical trial reports for Engerix-B, which would permit ICAN to conduct its own analysis of the so-called "safety review period." ICAN refused this offer. FDA then closed the request, advising ICAN that the request did not reasonably describe the records sought.

FDA now moves for summary judgment in its favor under Rule 56. FDA's response to ICAN's FOIA request and subsequent communications was reasonable and should be upheld. Under 5 U.S.C. § 552(a)(3), a FOIA requester must reasonably describe the records sought. A request that does not reasonably describe the requested records is a nullity that does not give rise

to a disclosure obligation under FOIA. Furthermore, a requester who does not reasonably describe the records fails to exhaust the required administrative process.

FDA's determination that it could not respond to ICAN's FOIA request, as written, was reasonable and appropriate. ICAN's request failed to reasonably describe the requested subset of Engerix-B vaccine clinical trial records, because Plaintiff insisted on asking for trials with "a safety review period longer than seven days following administration" of the vaccine. FOIA was not intended to permit requesters to commandeer agency staff to perform substantive review and analysis, as would be required to respond to ICAN's request, as written. Furthermore, the agency explained to ICAN that it was employing undefined and indeterminate terms that left the requested records in doubt, but ICAN refused to correct the issue, despite adequate notice.

Moreover, FDA attempted to resolve the issue through a broader disclosure of *all* of the pre-licensure clinical trials for Engerix-B, which would have permitted ICAN to perform its own analysis and categorize the records in the manner that it sees fit. ICAN refused FDA's reasonable proposal, effectively insisting on asking the government to sift through records using vague terms that are not criteria by which the relevant records are categorized. This resulted in the agency's determination that no records could be produced in response to ICAN's request. Because ICAN's request failed to reasonably describe the records it sought, and because FDA's response was appropriate, summary judgment should be entered in FDA's favor.

BACKGROUND

At issue in this action is a FOIA request that ICAN submitted to FDA dated June 21, 2019. Declaration of Suzann Burk ("Burk Decl.") ¶ 9 & Ex. A. The request sought:

> A copy of the report for each clinical trial relied upon by the FDA to approve Engerix-B for babies and children in 1989 that had a safety review period longer than seven days following administration of this vaccine.

Id. Upon review of the request, FDA staff determined that the requested records "would likely be included in the 'clinical trial reports' submitted by the sponsor in the original product application file for the vaccine Engerix-B, licensed in 1989 and used to prevent Hepatitis B infection." *Id.* ¶ 10. FDA determined that the relevant product application file, located in Silver Spring, Maryland, contained about 3,000 hard-copy pages of "clinical trial reports." *Id.* ¶ 12. These records would have to be scanned into electronic format to be reviewed and redacted by FDA's FOIA staff. *Id.* ¶ 13.

However, FDA determined that its normal procedures for searching for responsive records—including the use of specific search terms or relying on the file's organizational structure, *see id.* ¶ 15—would not be practicable to reasonably "identify 'clinical trial reports' for the Engerix-B vaccine that have 'a safety review period of longer than seven days,'" as ICAN requested. *Id.* ¶ 16. "To determine if a clinical trial report had a 'safety review period of longer than seven days,' [FDA] employees would have to manually review the records and interpret the records using the unclear criteria proposed by the requester, which are not defined by FDA regulations." *Id.*

FDA determined that it could not reasonably search for records responsive to ICAN's request, as drafted, as set forth in further detail below and in the attached declaration. *See id.* ¶¶ 17-21. Accordingly, FDA exchanged correspondence with ICAN at the administrative stage in an effort to clarify the request so that it could reasonably respond. On July 9, 2019, FDA sent an e-mail which stated in relevant part:

> The subject request[] do[es] not reasonably describe the records that you are seeking in a way that the records can be identified and located. Per our regulation in Title 21 CFR 20.40(b)[,] "A request should include all pertinent details that will help identify the records sought." Although you have identified the brand name of the vaccine of interest, as well as a date range, you have not provided information related to the clinical trial(s) for which you are seeking reports in a

> way that allows us to search our record systems without reading all the records in the application file and trying to identify which clinical studies may have had "a safety review period longer than 7 days."

Burk Decl. ¶¶ 22-23 & Ex. B-1.

On July 12, counsel for ICAN clarified that Plaintiff was seeking "pre-licensure clinical trials," but continued to request only records regarding trials "that had a safety review period longer than seven days." *Id.* ¶ 24 & Ex. B-2 (bold in original e-mail omitted). FDA responded by telephone and a follow-up e-mail, stating that "we are unable to search or locate records by information that may be included in the records, i.e. '*that had a safety review period longer than seven days.*'" *Id.* ¶ 25 & Ex. B-3 (italics in original e-mail). Instead, FDA proposed that ICAN amend the request to seek "[t]he clinical trial reports submitted by the sponsor for the original [Biologics Licensing Application] for Engerix B (STN 103239/0)[.]" *Id.* (italics omitted).

FDA was proposing to provide the full set of the pre-licensure clinical trial reports for Engerix-B, but ICAN refused this proposed modification. *Id.* ¶¶ 26-27 & Ex. B-4. Accordingly, FDA advised ICAN that it was closing the request because it was "unable to search or locate records in the way in which you describe the records." *Id.* ¶ 28 & Ex. C.

ICAN filed this suit on January 24, 2020. Dkt. No. 1. After FDA answered the complaint, ICAN filed the operative amended complaint on March 17, 2020. Dkt. No. 9. FDA answered the amended complaint on March 24, 2020. Dkt. No. 10.

ARGUMENT

I. FOIA Legal Standards

"Summary judgment is the procedural vehicle by which most FOIA actions are resolved." *NRDC v. Dep't of Interior*, 73 F. Supp. 3d 350, 355 (S.D.N.Y. 2014) (quotation marks omitted). "In resolving summary judgment motions in a FOIA case, a district court proceeds primarily by affidavits in lieu of other documentary or testimonial evidence." *Long v.*

OPM, 692 F.3d 185, 190 (2d Cir. 2012).[1] "Affidavits submitted by an agency are accorded a presumption of good faith," and a court may award summary judgment if the affidavits provided by the agency are "adequate on their face." *Carney v. DOJ*, 19 F.3d 807, 812 (2d Cir. 1994) (quotation marks omitted).

"FOIA was enacted to promote honest and open government and to . . . advance a general philosophy of full agency disclosure." *Grand Central P'ship, Inc. v. Cuomo*, 166 F.3d 473, 478 (2d Cir. 1999) (quotation marks omitted). However, "[t]he duties that FOIA imposes on agencies . . . apply only once an agency has received a proper FOIA request." *Citizens for Responsibility & Ethics in Washington v. FEC*, 711 F.3d 180, 185 n.3 (D.C. Cir. 2013). That is, "[a]n agency's disclosure obligations under the FOIA are triggered by its receipt of a request that 'reasonably describes [the requested] records' and 'is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed.'" *Davis v. FBI*, 767 F. Supp. 2d 201, 204 (D.D.C. 2011) (quoting 5 U.S.C. § 552(a)(3)(A)) (second alteration in *Davis*).

II. FDA Properly Determined That ICAN's Request Failed to Reasonably Describe the Records Sought

A. A FOIA Request That Reasonably Describes the Records Sought Is a Prerequisite to Relief Under FOIA

Before an agency is required to release records under FOIA, a requester must make a proper FOIA request with the agency. For a FOIA request to be proper, the request must "reasonably describe[]" the records sought under 5 U.S.C. § 552(a)(3)(A). *See Gillin v. IRS*, 980

[1] Courts in this district have deemed the submission of statements pursuant to Local Rule 56.1 to be unnecessary in FOIA matters. *See, e.g., N.Y. Times Co. v. DOJ*, 872 F. Supp. 2d 309, 314 (S.D.N.Y. 2012) ("The general rule in this Circuit is that in FOIA actions, agency affidavits alone will support a grant of summary judgment, and Local Civil Rule 56.1 statements are not required." (brackets and quotation marks omitted)); *accord N.Y. Legal Assistance Grp. v. BIA*, 401 F. Supp. 3d 445, 449 (S.D.N.Y. 2019). In accordance with this practice, FDA has not submitted a Rule 56.1 statement in this matter.

F.2d 819, 822 (1st Cir. 1992) (FOIA "creates an obligation to respond to a request which 'reasonably describes' the records sought"). FDA FOIA regulations require that a FOIA request "reasonably describe the records being sought, in a way that they can be identified and located," and "should include all pertinent details that will help identify the records sought." 21 C.F.R. § 20.40(b).

"[A] request which fails to 'reasonably describe' the documents sought does not trigger a search of agency records." *Truitt v. Dep't of State*, 897 F.2d 540, 544 (D.C. Cir. 1990) (quoting 5 U.S.C. § 552(a)(3)) (brackets omitted); *accord Marks v. United States*, 578 F.2d 261, 263 (9th Cir. 1978) ("FOIA requires that federal agencies make records available only upon a request which 'reasonably describes' the records sought." (quoting 5 U.S.C. § 552(a)(3)); *Dale v. IRS*, 238 F. Supp. 2d 99, 104 (D.D.C. 2002) (an agency "is under no obligation to release records that have not been reasonably described"). Thus, "[a]n agency's obligation to process a request for records is predicated on the agency's receipt of a request which reasonably describes the records sought." *Sussman v. DOJ*, No. 03 Civ. 3618 (DRH) (ETB), 2006 WL 2850608, at *9 (E.D.N.Y. Sept. 30, 2006).

Moreover, it is well established that "exhaustion of administrative remedies is a mandatory prerequisite to a lawsuit under FOIA." *Wilbur v. CIA*, 355 F.3d 675, 676 (D.C. Cir. 2004) (quotation marks omitted); *accord Taggart v. OIG*, No. 10 Civ. 5447 (PGG), 2011 WL 13128214, at *11 (S.D.N.Y. Sept. 22, 2011) (collecting cases), *aff'd on other grounds*, 530 F. App'x 17 (2d Cir. 2013) (summary order). Some courts have framed the issue of whether the requested records are properly described in terms of administrative exhaustion—that is, "in order to exhaust administrative remedies, a plaintiff must make a valid FOIA request that," among other things, "reasonably describe[s] the records sought." *Manfredonia v. SEC*, No. 08 Civ.

1678 (SLT) (LB), 2009 WL 4505510, at *5 (E.D.N.Y. Dec. 3, 2009) (quotation marks omitted); *accord Freedom Watch, Inc. v. FBI*, No. 18 Civ. 1912, 2019 WL 108879, at *2 (D.D.C. Jan. 4, 2019) ("If a requester . . . does not comply with the statutory requirement to submit a request that reasonably describes the records sought, but nonetheless files suit, she is said to have failed to exhaust her administrative remedies, and she must file a perfected request before a court will compel the agency to respond." (quotation marks omitted)); *MacLeod v. DHS*, No. 15 Civ. 1792, 2017 WL 4220398, at *12 (D.D.C. Sept. 21, 2017) ("a plaintiff who has not presented a reasonably specific request for documents, in violation of th[e] agency's own FOIA regulations, can also be conceived of as having failed to exhaust available administrative remedies prior to bringing suit" (citing cases)); *Pinson v. DOJ*, 70 F. Supp. 3d 111, 118 (D.D.C. 2014) ("Where a FOIA requester failed to reasonably describe the records sought, the requester has failed to submit a proper request and therefore failed to exhaust administrative remedies such that summary judgment in favor of the government is appropriate.").

Regardless of the framework, however, it is clear that a requester must reasonably describe the records at issue before either (i) the agency has an obligation to search for or produce records, or (ii) a requester is entitled to bring suit. *See Marks*, 578 F.2d at 263; *Latham v. DOJ*, 658 F. Supp. 2d 155, 161-62 (D.D.C. 2009); *Roman v. CIA*, No. 11 Civ. 5944 (JFB) (WDW), 2013 WL 210224, at *6 (E.D.N.Y. Jan. 18, 2013).

The determination of whether a FOIA request reasonably describes the records at issue is "highly context-specific." *Am. Oversight v. EPA*, 386 F. Supp. 3d 1, 15 (D.D.C. 2019) (quotation marks omitted). The "linchpin inquiry is whether 'the agency is able to determine precisely what records are being requested.'" *Dale*, 238 F. Supp. 2d at 104 (quoting *Tax Analysts v. IRS*, 117 F.3d 607, 610 (D.C. Cir. 1997)).

B. ICAN'S Request Fails to Reasonably Describe the Records Sought

Here, FDA appropriately concluded that it could not search for pre-licensure clinical trial reports for the hepatitis B vaccine Engerix-B using the parameters contained in ICAN's request—with "a safety review period of longer than seven days." *See* Burk Decl. ¶ 9 & Ex. A. As FDA states in its declaration, "'safety review period' is not a defined term" in the relevant FDA regulations. *Id.* ¶ 17. The set of clinical trial reports for Engerix-B "do not have segregated information about a 'safety review period,' nor is the 'safety review period' a criterion that a [Biologics Licensing Application, or BLA] applicant would be required to use to categorize clinical trials of Engerix-B or other vaccines." *Id.* "Each BLA is unique; applicants design clinical trials to demonstrate, through observations of participants, both the safety and effectiveness of a vaccine." *Id.* "Thus, searching any BLA for a non-defined 'safety review period' can only be done by reading and interpreting the 'clinical trial reports' to determine how the applicant measured safety." *Id.* FDA also determined that it could not search for responsive trials using "longer than seven days" as a searchable term, and "[c]linical trial records are not organized in a way that can be readily sorted by such a time period." *Id.* ¶ 18. Thus, FDA's FOIA staff would have to individually interpret of each of the clinical trial reports in the Engerix-B file to attempt to ascertain whether it is responsive. *Id.* ¶ 19.

Further, Plaintiff's request employs "indefinite terms," Burk Decl. ¶ 20, which render a conclusive determination of responsiveness impossible. *See Yagman v. Pompeo*, 868 F.3d 1075, 1081 (9th Cir. 2017) (a FOIA request is impermissibly vague where the agency "could not know what records would be responsive"). In determining how to measure the "safety review" period, the agency would have to guess at what records are responsive: for instance, "vaccines such as Engerix-B often require more than one vaccination or administration of the product," and as a result, "a reviewer would need to determine if the seven-day period should be viewed to begin

with the first administration of the vaccine, the final administration of the vaccine, or some other option." Burk Decl. ¶ 20. This confirms that FDA would be unable "to determine precisely what records are being requested," and thus that the request does not "reasonably describe[]" the relevant records. *Kowalczyk v. DOJ*, 73 F.3d 386, 388 (D.C. Cir. 1996) (quotation marks omitted); *see Yagman*, 868 F.3d at 1081 (concluding that FOIA request failed to reasonably describe the records sought where agency "would need to engage in quite a bit of guesswork to execute [the plaintiff's] request"); *see also ACLU v. DHS*, 738 F. Supp. 2d 93, 103 n.1 (D.D.C. 2010) ("it was the plaintiff's obligation[] to describe the records sought with reasonable detail").

It is eminently sensible that FOIA requires a requester to reasonably describe records such that they be readily identifiable by an agency's FOIA staff, because FOIA was "not intended to permit the public to commandeer agency employees as research assistants." *Nat'l Sec. Counselors v. CIA*, 960 F. Supp. 2d 101, 160 n.28 (D.D.C. 2013); *accord Knowles v. U.S. Dep't of State*, 308 F. Supp. 3d 1, 8 (D.D.C. 2018), *aff'd*, 773 F. App'x 3 (D.C. Cir. 2019) (unpublished); *see Assassination Archives & Research Ctr., Inc. v. CIA*, 720 F. Supp. 217, 219 (D.D.C. 1989) (requests must be framed "with sufficient particularity . . . to enable the searching agency to determine precisely what records are being requested," because "FOIA was not intended to reduce government agencies to full-time investigators on behalf of requesters"), *aff'd in relevant part*, No. 89-5414, 1990 WL 123924 (D.C. Cir. Aug. 13, 1990) (per curiam).

Indeed, FOIA precludes a request like ICAN's, where a requester seeks to requisition agency staff to "review[] clinical protocols and examin[e] data tables, charts, or written summaries" to make scientific or medical determinations about the trials, to seek to respond to the FOIA request. Burk Decl. ¶ 19. "The assessment that would be needed to make these types of determinations—if one could be made at all—would be akin to the work of an FDA clinical or

medical regulatory reviewer, not a disclosure reviewer processing FOIA requests." *Id.* ¶ 21. But a request that would require the agency to perform such "sifting and analysis" goes beyond the "burden that the FOIA imposes on federal agencies." *Nat'l Sec. Counselors*, 960 F. Supp. 2d at 158; *see Robert v. CIA*, No. 02 Civ. 6788 (JS) (AKT), 2018 WL 1598611, at *6 (E.D.N.Y. Mar. 31, 2018) (concluding that a request that "required additional research" did not reasonably describe the records sought), *aff'd*, 779 F. App'x 58 (2d Cir. 2019) (summary order).

FOIA also does not require agencies "to maintain their records or perform searches which are not compatible with their own document retrieval systems." *Thomas v. Comptroller of the Currency*, 684 F. Supp. 2d 29, 33 (D.D.C. 2010) (quoting *Assassination Archives*, 720 F. Supp. at 219); *accord Flores v. DOJ*, No. 15 Civ. 2627 (JMA) (RLM), 2016 WL 7856423, at *9 (E.D.N.Y. Oct. 4, 2016), *report and rec. adopted*, 2017 WL 238425 (E.D.N.Y. Jan. 18, 2017), *aff'd*, 712 F. App'x 107 (2d Cir. 2018) (summary order). Here, FDA avers that a "'safety review period'" is not "a criterion that a BLA applicant would be required to use to categorize clinical trials of Engerix-B or other vaccines." Burk Decl. ¶ 17. Additionally, clinical trial records "are not organized in a way that can be readily sorted by . . . a time period," like the "longer than seven days" sought by ICAN, nor would such a constraint be amenable to the use of search terms. *Id.* ¶ 18. Again, FOIA simply does not require the kind of search that would be required for FDA to attempt to fulfil Plaintiff's request. *See, e.g.*, *Thomas*, 684 F. Supp. 2d at 33 (upholding agency's refusal to conduct a search because its files were categorized by the names of national banks and federal agencies, but the requester provided no information from which the relevant bank or agency could be determined).

Accordingly, ICAN's request failed to reasonably describe the records requested, and judgment should be granted to FDA on this ground. *See Roman*, 2013 WL 210224, at *6.

C. FDA Properly Attempted to Assist ICAN in Modifying Its Request, But ICAN Declined to Accept the Broader Set of Records FDA Offered

Courts have noted with approval the agency practice of engaging in "cooperative discussion to narrow and focus requests for the benefit of both the agency and the requester." *Am. Oversight*, 386 F. Supp. 3d at 15. However, "[s]uch discussions, as this action makes clear, may not always prove successful." *Id.*

Under FDA's FOIA regulations, if a request's description of the records sought "is insufficient to locate the records requested, [FDA] will so notify the person making the request and indicate the additional information needed to identify the records requested," and will make all "reasonable effort[s] . . . to assist in the identification and location of the records sought." 21 C.F.R. § 20.40(b); *see id.* § 20.50 ("[n]onspecific requests" or those that would require an unduly burdensome agency response may result in FDA's asking the requester "to be more specific and to narrow the request").

Here, once FDA determined that it could not perform a search in response to the request as drafted, FDA appropriately responded by trying to assist ICAN in amending its request so that FDA could process it. *See* Burk Decl. ¶¶ 22-27 & Ex. B-1 through B-4. "[A]n agency receiving a FOIA request is not required to divine a requester's intent," and "is not required to have 'clairvoyant capabilities' to discover the requester's need." *Amnesty Int'l USA v. CIA*, 728 F. Supp. 2d 479, 499 (S.D.N.Y. 2010) (quoting *Hudgins v. IRS*, 620 F. Supp. 19, 21 (D.D.C. 1985)). Because it could not ascertain precisely what records ICAN's request sought, FDA offered to produce a *broader* set of records than ICAN had initially requested. *See* Burk Decl. ¶¶ 25-26 & Ex. B-3. In its proposed modification, FDA offered to process the "full set of 'clinical trial reports' contained in the Engerix-B product application file that were submitted in support of the 1989 licensure" of the vaccine. *Id.* ¶ 26. "Plaintiff would then have been free to

sort and analyze the responsive records as it saw fit, including to make its own assessment regarding which 'clinical trial reports' had a 'safety review period longer than seven days.'" *Id.* But ICAN declined FDA's proposed modification and made no counterproposal, thereby "effectively reject[ing] [FDA's] offer to produce all 'clinical trial reports' contained in the original Engerix-B product application file." *Id.* ¶ 27 & Ex. B-4.

Thus, when FDA determined that it could not search for the records as ICAN requested them, it appropriately sought to conduct a broader search that would necessarily capture the responsive information within it. *See Pinson v. DOJ*, 80 F. Supp. 3d 211, 216 (D.D.C. 2015) (noting that, in appropriate circumstances, an agency may fulfil its responsibilities under FOIA by "conduct[ing] a broader search" than requested (citing *Greenberg v. U.S. Dep't of Treasury*, 10 F. Supp. 2d 3, 13 (D.D.C. 1998))). After ICAN refused to accept the reasonable modification (and broader scope) proposed by agency staff, FDA properly declined to conduct an indeterminate analysis based on the terms of ICAN's request. *See* Burk Decl. ¶¶ 16-21, 27-28. ICAN was not entitled to commandeer agency staff to perform ICAN's requested analysis in its stead. *See Nat'l Sec. Counselors*, 960 F. Supp. 2d at 160 n.28 (FOIA does not require agencies to produce "a listing that summarizes or describes the contents of an electronic database," which "would permit the public to requisition the resources of government agencies in a way that the FOIA did not intend"); *see also Hall & Assocs. v. EPA*, 83 F. Supp. 3d 92, 102 (D.D.C. 2015) (an agency is not required to "answer questions disguised as a FOIA request, nor conduct research in response to a FOIA request" (citation and quotation marks omitted)). Nor was FDA required to further attempt to "divine [ICAN's] intent," *Amnesty Int'l*, 728 F. Supp. 2d at 499, or to "engage in . . . guesswork to execute [ICAN's] request," *Yagman*, 868 F.3d at 1081.

Accordingly, FDA's determination that ICAN's request did not reasonably describe the records, and its subsequent decision to close the request when ICAN refused to modify it, *see* Burk Decl. ¶¶ 16-29, were proper and should be upheld.

* * *

For the foregoing reasons, ICAN's FOIA request, as drafted, failed to reasonably describe the records sought. FDA's response to the request appropriately sought clarification and, subsequently, proposed a broadening of the scope of the request that would have provided ICAN all of the clinical trial information it needed to conduct its own analysis. ICAN refused this modification. Because FDA's response was reasonable and appropriate in light of the circumstances, the Court should grant summary judgment in FDA's favor.

CONCLUSION

For the foregoing reasons, the Court should grant Defendant's motion and enter judgment in FDA's favor under Rule 56 of the Federal Rules of Civil Procedure.

Dated: July 10, 2020
New York, New York

Respectfully submitted,

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